

# LIFEGARD® II

Patient Monitor



SERVICE MANUAL

LIFEGARD II  
Patient Monitor  
Service Manual  
Model: AN4300

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**CE Marking**

**Europe**

The following product and accessories from Analogic Corporation carry the  mark to Council Directive 93/42/EEC.

CE Product: AN4320, AN4320P, AN4321P, AN4322P, AN4323P

Accessories from other companies other than Analogic Corporation carry CE markings appropriate to the accessory.

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Analogic Part Number: 16-00261-01 Rev. 00

***Domestic Issued Patents and Applications for Patent Marking for Oridion  
Microstream® Technology***

<b><u>U.S. Patent Number</u></b>	<b><u>Title</u></b>
1. 4,755,675	Gas Analyzer & A Source of IR Radiation Therefor
2. 5,300,859	IR Radiation Source & Method for Producing Same
3. 5,657,750	Fluid Filtering Device Utilizable with Gas Monitors
4. 5,857,461	Multiple Channel Sample Port
5. 6,428,483	Waveform Interpreter for Respiratory Analysis
6. 6,422,240	Oral/Nasal Cannula
7. 6,437,316	Fluid Analyzer with Tube Connector Verifier

This product is covered by one or more of the following U.S.A. patents and their foreign equivalents: 4,755,675; 5,300,859; 5,657,750; 5,857,461; 6,428,483; 6,422,240; and 6,437,316. Additional patents pending. Japanese patent 1,980,816.

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**NOTE: The information contained in this manual is valid only for the operating version(s) printed in the inside front cover.**

The LIFEGARD II Service Manual contains all the information needed to support the LIFEGARD II monitor for the service, diagnosis, removal and replacement of field replaceable parts.

This Service Manual supports Monitor Software Version 1.xx

If the software version of your produce is not in the range from 1.00 to 1.99, please contact your sales representative to obtain addendum pages or a replacement manual that describes the operation of your version of the product. The monitor's software revision number can be located during the boot up sequence in the lower center of the screen.

## TABLE OF CONTENTS

1.0	Introduction	1-1
1.1	General Safety Information	1-1
1.2	General	1-1
1.3	LIFEGARD II Patient Monitor Description	1-1
1.4	Features and Options	1-2
1.5	Front Panel Description	1-3
1.6	Front of Monitor	1-4
1.7	Rear of Monitor	1-5
1.8	Screen Display	1-6
1.9	Additional Documentation	1-6
2.0	Safety	2-1
2.1	Proper Use	2-1
2.2	Warnings, Cautions, and Notes	2-1
2.3	Warnings	2-2
3.0	Site Preparations	3-1
3.1	General	3-1
3.2	General Site Preparation Safety Information	3-1
3.3	Site Preparation Guidelines	3-2
3.4	Safety Precautions	3-2
3.5	Preparing to Use the Monitor	3-2
3.6	Monitor Disposal	3-3
3.7	Unpacking the Monitor	3-3
3.8	Checking the Shipment	3-3
3.9	Returning System Components	3-4
4.0	Maintaining the Monitor	4-1
4.1	General	4-1
4.2	Maintenance Safety Information	4-1
4.3	Objectives	4-1
4.4	Concepts	4-1
4.5	Recommendations for Maintenance Frequency	4-2
4.6	Cleaning	4-3
4.7	Battery Maintenance	4-4
5.0	Configuring the Power-up Defaults Menu	5-1
5.1	General Safety Information	5-1
5.2	Power-up Defaults Menu	5-1

6.0	Testing the Monitor	6-1
6.1	General	6-1
6.2	Testing Safety Information	6-1
6.3	Objectives	6-1
6.4	Testing Checklist	6-2
6.5	Recommendations for Testing Frequency	6-3
6.6	Test Map	6-4
6.7	Equipment	6-5
6.8	Serial Numbers	6-6
6.9	Visual Test	6-6
6.10	Passwords	6-6
6.11	Functionality Assurance Tests	6-7
6.12	Preventive Maintenance Tests	6-9
6.13	Performance Procedures	6-14
6.14	Patient Safety Tests	6-24
7.0	Troubleshooting	7-1
7.1	General Troubleshooting Safety Information	7-1
7.2	Objectives	7-1
7.3	Concepts	7-1
7.4	Part 1 Troubleshooting Checklist	7-2
7.5	Part 2 Isolating and Solving Monitor Problems	7-3
7.6	Part 3 Using Support Functions	7-7
8.0	Disassembly	8-1
8.1	Introduction	8-1
8.2	Tools Requires	8-1
8.3	Disassembly Safety Information	8-2
8.4	Disassembly Procedures	8-2
8.4.1	Closed Case Disassembly Procedures	8-2
9.0	Spare Parts	9-1
9.1	Small Parts Kit	9-1
9.2	LIFEGARD II Top Level Assembly	9-1
9.3	Front Panel Assembly	9-2
9.4	Front Case Kit	9-3
9.5	Display Kit	9-3
9.6	Rear Panel Assembly	9-4
9.7	Rear Case Kit	9-6
9.8	Chassis Case Kit	9-6
9.9	Additional Spare Modules	9-6
10.0	Packing for Shipment	10-1
10.1	General Instructions	10-1
10.2	Repacking the Original Carton	10-1
10.3	Repacking in a Different Carton	10-1

11.0 RS-232 Interface .....	11-1
11.1 General RS-232 Safety Information .....	11-1
11.2 The RS-232 Interface .....	11-1
12.0 Theory of Operation and System Architecture .....	12-1
12.1 General .....	12-1
12.2 System Overview .....	12-1
12.3 Block Diagram .....	12-1
12.4 Isolated Front End .....	12-3
12.5 NIBP Front End .....	12-3
12.6 Power System .....	12-3
12.7 Microprocessor, Memory and Control .....	12-3
12.8 Display .....	12-3
12.9 Keypad .....	12-3
12.10 Navigation Wheel .....	12-4
12.11 RS-232 I/O .....	12-4
12.12 Speaker .....	12-4
12.13 USB Printer Interface .....	12-4
12.14 Recorder .....	12-5
12.15 ECG Processing .....	12-5
12.16 ICG Processing .....	12-5
12.17 Respiration Processing .....	12-5
12.18 NIBP Processing .....	12-5
12.19 SpO <sub>2</sub> Processing .....	12-6
12.20 CO <sub>2</sub> Processing .....	12-6
12.21 Temperature Processing .....	12-6
13.0 Specifications .....	13-1
13.1 General .....	13-1
13.2 Hardware Specifications .....	13-1
13.3 Safety Standards .....	13-1
13.4 Audible Alarms .....	13-2
13.5 Electrical .....	13-2
13.6 Environmental .....	13-3
13.7 Measuring and Displaying Parameters .....	13-3
14.0 Technical Services and Support .....	14-1
14.1 General .....	14-1
14.2 Obtaining Technical Assistance .....	14-1
14.3 Return Material Procedure .....	14-1

# Introduction

## 1.1 General Safety Information

---

**WARNING**

This monitor is not intended for neonates.

---

**WARNING**

If you connect the monitor to any instrument, verify proper operation before clinical use. Refer to that instrument's operator's manual for full instructions.

---

**WARNING**

Accessory equipment connected to the monitor's data interface must be certified according to IEC Standard 60950 for data-processing equipment or IEC Standard 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 systems requirements.

---

**WARNING**

Anyone who connects additional equipment to the signal input port or signal output port configures a medical system and is, therefore, responsible to ensure that the system complies with the requirements of system standard IEC Standard 60601-1-1. If in doubt, contact the Life Care Systems Support Group (see page 14-1).

---

**NOTE**

The monitor and its accessories must be tested by qualified service personnel at regular intervals to verify proper operation, according to the procedures of the user's institution.

Other important safety information is located in this Service Manual where appropriate.

---

## 1.2 General

This manual contains information for servicing the LIFEGARD II patient monitor. Only qualified service personnel should service this monitor. Before servicing the monitor, carefully read the LIFEGARD II Operator's Manual for a thorough understanding of operation.

## 1.3 LIFEGARD II Patient Monitor Description

The purpose and function of the LIFEGARD II family of patient monitors is to monitor ECG, heart rate, non-invasive blood pressure (NIBP), functional arterial oxygen saturation (SpO<sub>2</sub>), respiration rate, temperature and carbon dioxide<sup>1</sup> (CO<sub>2</sub>) for adult and pediatric patients in the physician's office, hospital areas and hospital-type facilities, such as clinics, and to non-invasively evaluate the hemodynamic status of adult patients in either the hospital or physician's office environment based on the measurement of thoracic electrical bioimpedance (TEB).

The intended users of the LIFEGARD II patient monitors are clinicians and nursing staffs within hospital, out-patient, and ambulatory settings. This monitor is not intended for helicopter transport or home use.

The physical and operational characteristics of the monitor are described in the LIFEGARD II Operator's Manual.



## 1.4 Features and Options

The LIFEGARD II is available in the following models:

Model	Description
AN4320	Can be used to monitor ECG, heart rate, non-invasive blood pressure (NIBP), respiration rate and temperature.
AN4320P	Includes all the features and functionality found in the AN4320, but can also generate recordings and print them to the optional, internal strip recorder. See <i>Recording and Printing Trends</i> for more information on recorders.
AN4321P	Includes all the features and functionality found in the AN4320 but also integrates a EtCO <sub>2</sub> measurement from Oridion. Can be used as a general-purpose patient monitor, or for procedural sedation in anesthesia. Can generate recordings and print them to the optional, internal strip recorder. See <i>Recording and Printing Trends</i> for more information on recorders.
AN4322P	Includes all the features and functionality found in the AN4320 but also integrates ICG (Impedance Cardiography). It can be used to generate recordings on the strip chart recorder. See <i>Recording and Printing Trends</i> for more information on recorders. The AN4322P can also print reports on an external ink-jet printer, if available. See operator's manual, Chapter 16 for more information on printing reports. Note — The AN4322P in ICG mode does not monitor respiration.
AN4323P	The AN4323P model offers both the EtCO <sub>2</sub> and ICG capabilities. The cable configuration determines which function is currently being used. Also includes internal strip recorder.

1. Carbon Dioxide monitoring is available in the AN4321P and the AN4323P models only.

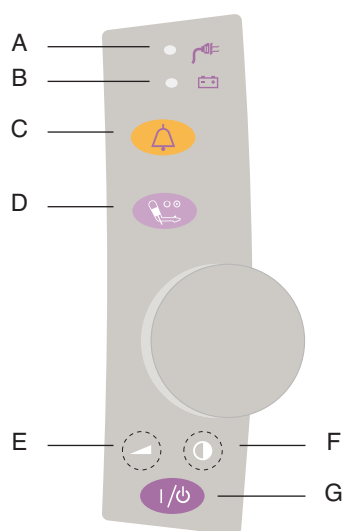


The measurement parameters and features for each model are indicated below.

Model	Description	Parameters							Printout	
		ECG	NIBP	Temp	SpO <sub>2</sub>	Respiration	EtCO <sub>2</sub>	Hemo	Recorder	USB Printer Interface
AN4320	Basic	✓	✓	✓	✓	✓				
AN4320P	Basic w/recorder	✓	✓	✓	✓	✓			✓	
AN4321P	Basic w/EtCO <sub>2</sub>	✓	✓	✓	✓	✓	✓		✓	
AN4322P	Basic w/ICG	✓	✓	✓	✓	✓		✓	✓	✓
AN4323P	Basic w/EtCO <sub>2</sub> & ICG	✓	✓	✓	✓	✓	✓	✓	✓	✓

## 1.5 Front Panel Description

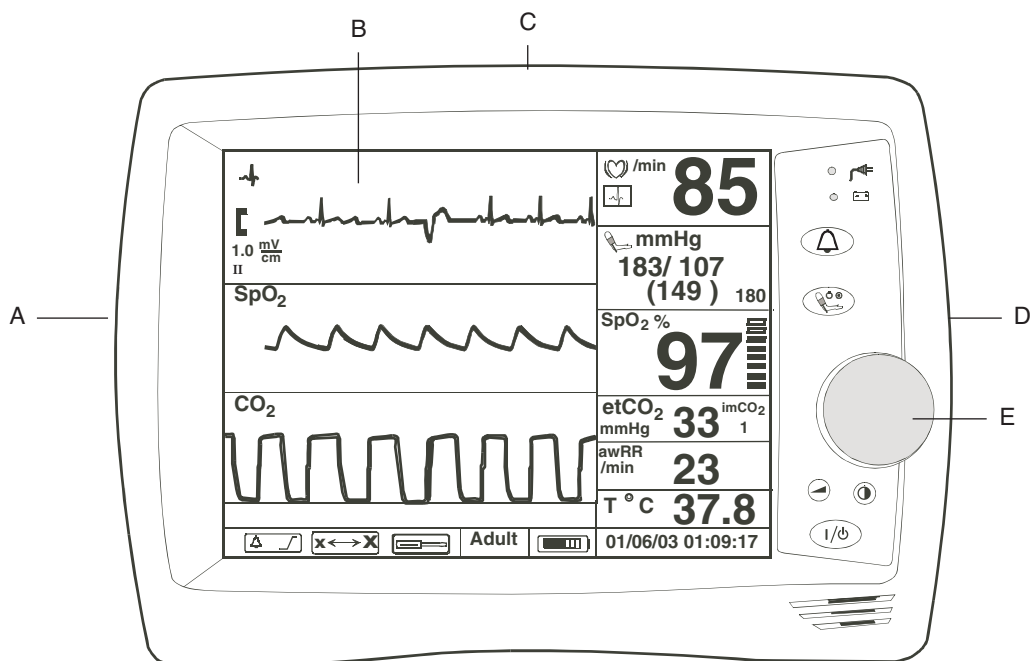
The following diagram illustrates the controls located on the LIFEGARD II front panel.



Callout	Description
A	AC LED
B	Battery LED
C	Audio Alarm Control Button
D	NIBP Button
E	Volume Button
F	Contrast Button
G	On/Standby Button

## 1.6 Front of Monitor

Use the following diagram to familiarize yourself with the main features of the LIFE-GARD II monitor. The recorder module and all patient input connectors are located on the monitor's side panels.




Callout	Description
A	Patient Monitoring Input Connectors
B	Main Monitoring Screen
C	Handle
D	Recorder (optional feature)
E	Navigation Wheel

### Patient Monitor Connectors

All the patient input connectors on the LIFE-GARD II monitor are classified as type CF, which specifies their degree of protection against electrical shock. All are rated as defibrillator-proof. The following heart symbol is on the side of the monitor where the patient monitoring input connectors are located.



Each connection is identified by a unique icon describing the parameter being monitored through that connector. They are illustrated in the following table.

Monitored Parameter	Connector Type	Icon
ECG and Respiration	Use with LIFEGARD II ECG lead cable.	<b>ECG/Resp</b>
vECG and ICG	Use with LIFEGARD II ICG lead cable.	<b>ECG/Resp/ICG</b>
Temperature	Use Analogic temperature probes	<b>T</b>
SpO <sub>2</sub>	Use with Analogic sensors and sensor extension cables.	<b>SpO<sub>2</sub></b>
NIBP	Compatible with recommended Analogic blood pressure tubing for LIFEGARD II.	
EtCO <sub>2</sub>	Compatible with Oridion Microstream® accessories.	<b>CO<sub>2</sub></b>

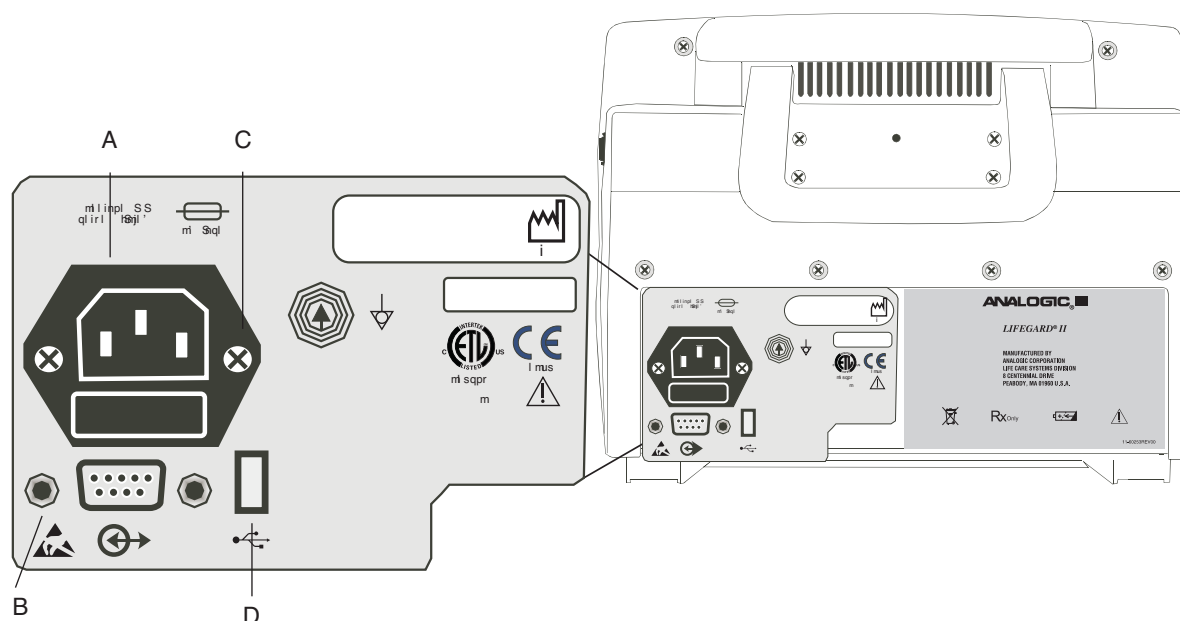
**WARNING**




Use only the approved accessories for the LIFEGARD II patient monitor.

## 1.7 Rear of Monitor

The following diagram is of the rear panel. See Chapter 2 for an explanation of the symbols located on this panel.

The LIFEGARD II's rear panel is shown below with its four connectors: USB, Equipotential, AC input and RS-232.

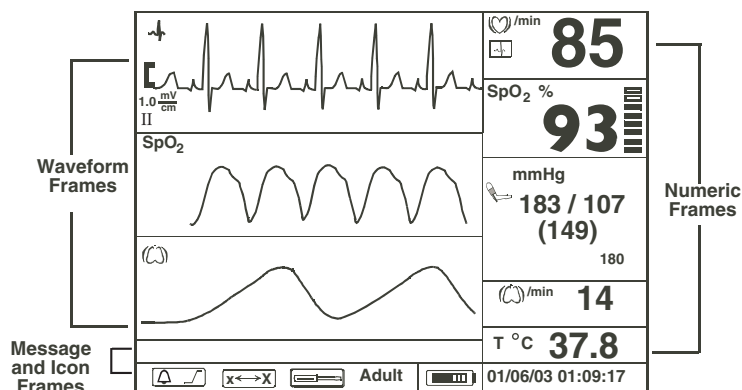


Callout	Connector	Connector Type	Label
A	AC Input	3-line connector IEC 320 receptacle  See "AC Power on page 4-3 for more information.	<b>100 - 240V ~ 50 - 60 Hz 1A</b>
B	RS-232 I/O	DB-9 (male)	
C	Equipotential Ground Post	Equipotential The equipotential grounding post may be used by facilities as required by their procedures.	
D	USB I/O	USB Host Connector	

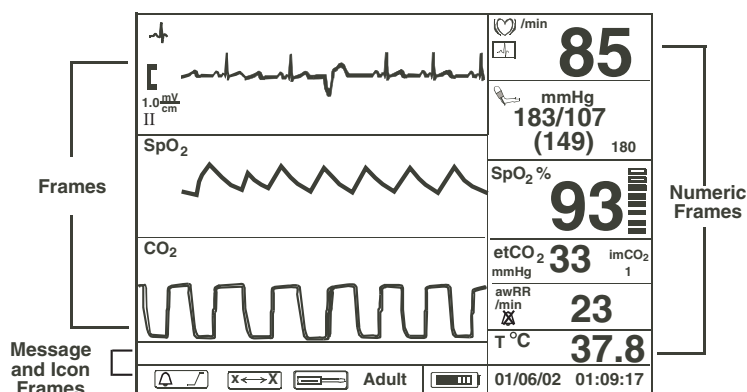
## 1.8 Screen Display

The LCD displays parameter values, real-time waveforms, alarm messages and screen selection icons.

- Numeric frames displays icons and numeric values of real-time physiologic parameter.
- Waveform frames displays real-time waveforms, graphical trend, or tabular trend data.
- Message and Icon frames displays alarm messages and screen selection icons.



Standard Model



Sedation Model

## 1.9 Additional Documentation

To use the information in this service manual effectively, the operation of the monitor and its accessories must be fully understood. Refer to the LIFEGARD II Operator's Manual to obtain an understanding of the monitor and its accessories.

# Safety

## 2.1 *Proper Use*

This monitor is not intended for neonates. ICG mode is intended primarily for adult patients depending on body size.

Ensure that the monitor is in proper working condition before clinical use. If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternative means and then with the monitor to make sure it is working properly.

If you connect the monitor to any instrument, verify proper operation before clinical use. Refer to that instrument's manual for full instructions.

Accessory equipment connected to the monitor's data interface must be certified according to IEC 60950 for data-processing equipment or IEC 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 60601-1-1 systems requirements.

Anyone who connects additional equipment to the signal input port or signal output port configures a medical system and is therefore responsible to ensure that the system complies with the requirements of system standard IEC 60601-1-1.

Respiration can only be monitored with an ICU ECG cable set, not with an OR ECG cable set. This is because of the higher internal impedance of the OR cable set, required for use if electro-surgery is being performed.

The care and handling of all accessories should be in accordance with local hospital guidelines, policies, and procedures.

### **NOTE**

The monitor and its accessories must be tested by qualified service personnel at regular intervals to verify proper operation, according to the procedures of the user's institution.

## 2.2 *Warnings, Cautions, and Notes*

The precautions are grouped into two (2) main categories, **WARNINGS** and **CAUTIONS**.

In addition, the manual highlights **Notes** of significant information relevant to the monitor display, operator instruction, or operator action being described in the text.



Warnings advise against certain actions or situations that could result in personal injury or death.



Cautions advise against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

Notes provide useful information regarding a function or procedure.

## 2.3 Warnings

The following are warnings that define precautions that must be observed to avoid injury to personnel. Some of these precautions are specific to particular operator actions. They will appear in the text. Others may be of a “general-purpose” nature, and may not be duplicated in the many places in which they may be relevant.

---

### WARNING



Explosion Hazard. Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.

---

### WARNING



Electric Shock Hazard. Covers should be removed only by qualified service personnel. There are no user-serviceable parts inside.

---

### WARNING



Do not connect accessory equipment to the monitor's data interface if it is not certified according to the IEC 60950 for data-processing equipment or IEC 60601-1-1 for electromedical equipment.

---

### WARNING



Route patient cabling to reduce the possibility of patient entanglement or strangulation.

---

### WARNING



This monitor is not intended for use on neonatal patients.

---

### WARNING



Do not place the monitor in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient connections because disconnection could then result in the monitor dropping on the patient.

---

### WARNING



To ensure patient electrical isolation, connect only to other equipment that provides patient electrical isolation.

---

### WARNING



Do not use extension cords to connect the monitor to electrical outlets.

---

### WARNING



Do not use the monitor during MRI (magnetic resonance imaging) scanning. Induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of the monitor's measurements.

---

### WARNING



To ensure optimal battery performance, the monitor must be connected to AC power for 14 hours prior to first use of battery power. Your monitor can be used during the charging time because the battery is still being charged even if the monitor is turned on.

**WARNING**

Electromagnetic interference may cause disruption of performance. Protect the monitor from sources of intense electromagnetic radiation. This device has been designed to provide resistance to electromagnetic interference. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the healthcare and home environments (such as cellular phones, mobile two-way radios, electrical appliances) it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performances of this device. Disruption may be evidenced by erratic readings, cessation of operation or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions should be taken to eliminate the source. If assistance is required, contact the Life Care Systems Support Group.

**WARNING**

All IEC/EN 60950 equipment, including printers, must be positioned no closer than 1.5 meters to the patient's bed.

**WARNING**

The monitor is not intended for use on more than one patient at a time.

**WARNING**

Use only the supplied power cord. If in doubt about the integrity of the grounding of the AC power source, operate the monitor only from its battery

**WARNING**

Use only the approved accessories for the LIFEGARD II patient monitor.

**WARNING**

Do not connect this monitor to any other equipment or device other than those specified in this Operator's Manual.

**WARNING**

If the battery is defective, the loss-of-monitoring alarm may fail to sound.

Neither the Print-On-Alarm nor the Nurse Call signal initiates when the monitor detects a loss-of-monitoring state.

If an alarm condition (except those leading to a loss-of-monitoring alarm) occurs while the monitor is in the Audio Off state, the only alarm indication are visual displays related to the alarm conditions.

**WARNING**

Use only Analogic ECG leads with the LIFEGARD II monitor. Other ECG cables and leads can cause improper performance and/or provide inadequate protection during defibrillation.

**WARNING**

Do not use damaged ECG leads.

**WARNING**

Do not immerse ECG leads completely in water, solvents, or cleaning solutions because the connectors are not waterproof.

**WARNING**



When you are connecting the electrodes or the patient cable, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, ensure that all of the ECG electrodes are attached to the patient to prevent them from contacting conductive parts or earth.

---

**WARNING**



Sterilization is not recommended for this monitor, related products, accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies.

---

**WARNING**



Respiration can only be monitored with an ICU ECG cable set, **not** with an OR ECG cable set. This is because of the higher internal impedance of the OR cable set, required for use if electro-surgery is being performed.

---

**WARNING**



Ensure that conductive portions of the electrodes, leads and cable do not come into contact with any other conductive parts.

---

**WARNING**



For pacemaker patients, the monitor can continue to count pacemaker rate during cardiac arrest or some arrhythmias. Do not rely entirely upon the monitor's alarm. Keep pacemaker patients under close surveillance.

---

**WARNING**



Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. Such transients may be minimized by proper electrode and cable placement, as specified in this manual and electrode directions for use.

---

**WARNING**



ECG cables may be damaged when connected to a patient during defibrillation. Check cables that have been connected to a patient during defibrillation for functionality before using them again

---

**WARNING**



Monitoring with the Pacer Detect feature enabled does not normally affect the monitoring of non-pacemaker patients. However, in some instances, if the patient does not have a pacemaker, it can be desirable to turn the detection function Off so that artifacts in the waveform are not mistaken for a pacemaker signal.

---

**WARNING**



Do not use with minute-ventilation adaptive pacemakers. The injected current may cause this type of pacemaker to malfunction and set the pacemaker rate too high.

---

**WARNING**



When using Electro-Surgical equipment, never place ECG electrodes near to the grounding plate of the ES device, as this can cause a lot of interference on the ECG signal.

---

**WARNING**



Use only Analogic recommended SpO<sub>2</sub> sensors for SpO<sub>2</sub> measurements. Other SpO<sub>2</sub> sensors may cause improper performance.



**WARNING**

Tissue damage can be caused by incorrect application or use of an SpO<sub>2</sub> sensor. For example by wrapping the sensor too tightly or by applying supplemental tape. Inspect the sensor site as directed in the sensor directions for use to ensure skin integrity and correct positioning and adhesion of the sensor.

---

**WARNING**

Do not use damaged SpO<sub>2</sub> sensors. Do not use an SpO<sub>2</sub> sensor with exposed optical components. Do not immerse sensor completely in water, solvents, or cleaning solutions because the sensor and connectors are not waterproof. Do not sterilize SpO<sub>2</sub> sensors by irradiation, steam, or ethylene oxide. Refer to the cleaning instructions in the directions for use for reusable SpO<sub>2</sub> sensors.

---

**WARNING**

Inaccurate readings could result if a sensor is used incorrectly. Before using a sensor, carefully read and understand the sensor directions for use.

---

**WARNING**

Although some sensors are also specified for use on very small patients (neonates) as well as infant, pediatric and adult patients, the monitor is not intended for use on neonatal patients.

---

**WARNING**

Using an SpO<sub>2</sub> sensor during MR imaging can cause severe burns. Minimize this risk by positioning the cable so that no inductive loops are formed. In the sensor does not appear to be operating properly, remove it immediately from the patient.

---

**WARNING**

Do not use disposable sensors on patients who have a known allergic reaction to the adhesive.

---

**WARNING**

Reusable sensors must be moved to a new site at least every 4 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.

---

**WARNING**

Do not alter or modify the AN4K-AC001 Nellcor Durasensor. Alterations or modifications may affect performance or accuracy.

---

**WARNING**

As with all medical equipment, carefully route cables to reduce the possibility of patient entanglement or strangulation.

---

**WARNING**

Carefully apply the sensor to the patient, as described in Chapter 8 of the operator's manual. The sensor may be connected directly to the Analogic LIFEGARD II's side panel connector, identified with the SpO<sub>2</sub> icon. Typically, however, it is more convenient to connect the sensor to the monitor by using an SpO<sub>2</sub> extension cable (P/N AN4K-AC004). Periodically check to see that the sensor remains properly positioned on the patient and that skin integrity is acceptable.

**WARNING**

Inaccurate SpO<sub>2</sub> measurements may be caused by:

- Incorrect sensor application or use
- significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin)
- intravascular dyes such as indocyanine green or methylene blue
- exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight
- excessive patient movement
- high-frequency electrosurgical interference and defibrillators
- venous pulsations
- placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
- there is arterial occlusion proximal to the sensor
- the patient is in cardiac arrest or is in shock

---

**WARNING**

Loss of pulse signal can occur in any of the following situations:

- the sensor is too tight
- there is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight
- a blood pressure cuff is inflated on the same extremity as the one to which an SpO<sub>2</sub> sensor is attached

---

**WARNING**

Correlation: The EtCO<sub>2</sub> readings do not always correlate closely with paCO<sub>2</sub> values, especially in patients with pulmonary disease, pulmonary embolism or inappropriate ventilation.

---

**WARNING**

Do not measure EtCO<sub>2</sub> in the presence of pharmaceuticals in aerosols.

---

**WARNING**

Danger - explosion hazard - Microstream<sup>®</sup> measurement should not be used in the presence of flammable anesthetics such as:

- Flammable anesthetic mixture with air
- Flammable anesthetic mixture with Oxygen or Nitrous Oxide

---

**WARNING**

EtCO<sub>2</sub> values for non-intubated patients using Microstream<sup>®</sup> accessories always tend to be lower than for intubated patients. If values appear extremely low, check whether the patient is breathing through the mouth or whether one nostril is blocked.

---

**WARNING**

Use only Microstream<sup>®</sup> accessories to ensure correct functioning of the EtCO<sub>2</sub> Microstream<sup>®</sup> measurement.

**WARNING**

When using the Microstream® EtCO<sub>2</sub> measurement on patients who are receiving or have recently received anesthetics, the outlet must be connected to a scavenging system or to the anesthesia machine/ventilator to prevent exposure of medical staff to anesthetics.

**WARNING**

Do not re-use, clean, or sterilize Microstream® EtCO<sub>2</sub> accessories as they are intended for single-patient, one-time use.

**WARNING**

Use only Analogic recommended blood pressure tubing and cuffs. Using other cuffs or tubing can result in inaccuracies.

**WARNING**

Do not use the monitor on patients who are linked to heart or lung machines.

**WARNING**

The monitor cannot operate effectively on patients who are experiencing convulsions or tremors.

**WARNING**

Inaccurate measurements can be caused by:

- incorrect cuff application or use, such as placing the cuff too loosely on the patient, using the incorrect cuff size, or not placing the cuff at the same level as the heart
- a leak in the cuff or tubing
- excessive patient motion

**WARNING**

The monitor displays results of the last blood pressure measurement until another measurement is completed. If a patient's condition changes during the time interval between measurements, the monitor does not detect the change or indicate an alarm condition.

**WARNING**

Sometimes, electrical signals at the heart do not produce a peripheral pulse. If a patient's beat-to-beat pulse amplitude varies significantly (for example, pulsus alternans, atrial fibrillation, rapid-cycling artificial ventilator), blood pressure and pulse rate readings can be erratic and an alternate measuring method should be used for confirmation.

**WARNING**

A patient's vital signs can vary dramatically during administration of agents affecting the cardiovascular system, such as those used to raise or lower blood pressure or raise or lower heart rate.

**WARNING**

As with all automatically inflatable blood pressure devices, continual cuff measurements can cause injury to the patient being monitored. Weigh the advantages of frequent measurement and/or use of stat mode against the risk of injury.

**WARNING**

In some cases, rapid, prolonged cycling of an oscillometric, non-invasive blood pressure monitor cuff has been associated with any or all of the following: ischemia, purpura, or neuropathy. Apply the oscillometric cuff appropriately, according to the manufacturer's directions for use, and check the cuff site and cuffed extremity regularly when blood pressure is measured at frequent intervals or over extended periods of time.

- Check the patient's limb on which the cuff is applied to assure that circulation is not constricted. Constriction of circulation is indicated by discoloration of the extremity. This check should be performed at the clinician's discretion at regular intervals based on the circumstances of the specific situation.
- Do not place the cuff on an extremity being used for intravenous infusion or any area where circulation is compromised or has the potential to be compromised.
- Do not apply the blood pressure cuff to the same extremity as the one to which an SpO<sub>2</sub> sensor is attached because the cuff inflation disrupts SpO<sub>2</sub> monitoring and leads to nuisance alarms.
- When in use on patients, ensure that heavy objects are not placed on the tubing. Avoid crimping or excessive bending, twisting, or entangling the tubes.

---

**WARNING**

Do not use STAT mode when using the thigh cuff to monitor NIBP. Use of this mode causes a loss-of-monitoring alarm and shuts down all monitor functionality.

---

**WARNING**

Be sure to follow the safety guidelines listed below:

- Use only Analogic specified sensors for the LIFEGARD II monitor.
- Do not use the thermometer if you see any signs of damage to the probe.
- When performing defibrillation or electrosurgery, there is a potential for signal corruption.

---

**WARNING**

The monitor is a respiration rate monitor only. Do not use it for Loss-of-Respiration detection or to monitor neonates.

---

**WARNING**

Respiration monitoring is suspended when in ICG mode.

---

**WARNING**

Keep patients under close surveillance when monitoring respiration. Respiration signals are sensitive to interference from radiated electromagnetic signals. Although unlikely, radiated electromagnetic signals from sources external to the patient and monitor might cause inaccurate respiration readings.

---

**WARNING**

Do not rely entirely on the monitor's respiration readings for patient assessment.

---

**WARNING**

If you permanently silence the respiration rate limits audible alarm (the crossed-bell is present), the Loss-of-Respiration signal audible alarm is also permanently silenced.

---

**WARNING**

ICG mode is not for use on neonatal or pediatric patients.

**WARNING**

The following patient conditions/anomalies may limit the accuracy of data:

- aortic valve regurgitation
- serious hypertension (MAP >130 mmHg)
- septic shock

**WARNING**

This system is not recommended for recording measurements during open heart surgery.

**WARNING**

Do not use on patients with minute-ventilation-rate adaptive pacemakers. The injected current may cause this type of pacemaker to malfunction and set the pacemaker rate too high.

**WARNING**

Interference from instruments near the patient and Electro-Surgical Unit interference can cause problems with the ICG wave.

**WARNING**

When using Electro-Surgical equipment, never place the ICG sensors near the grounding plate of the ES device as this can cause a lot of interference on the ICG signal.

**WARNING**

Cables and sensors:

- Do not use ICG cables or sensors if damaged.
- Do not sterilize ICG cables by irradiation, steam, or ethylene oxide. Refer to “Cable Care Instructions” on page 13-18 of the operator’s manual.
- Do not immerse ICG cables or sensors completely in water, solvents, or cleaning solutions.

**WARNING**

For pacemaker patients, the monitor may continue to count pacemaker pulses during cardiac arrest or some arrhythmias. Do NOT rely entirely upon the monitor’s alarms. Keep pacemaker patients under close surveillance.

**WARNING**

Ensure that conductive portions of the cable and electrodes do not come into contact with any other conductive parts.

**WARNING**

Use only Analogic supplied ICG cables with the LIFEGARD II. Other ICG cables may cause improper performance and/or provide inadequate protection during defibrillation.

**WARNING**

The continuous display of the B, C, and X marks on the ICG waveform enable you to ensure that the mode is operating properly. If one or more of the B, C, and X marks fail to display on the Signal Quality Indicator (SQI), your readings could be inaccurate and/or you may be unable to obtain accurate values for stroke volume and other hemodynamic parameters.

**WARNING**



Anyone who connects additional equipment to the signal input port or signal output port configures a medical system and is therefore responsible to ensure that the system complies with the requirements of system standard IEC 60601-1-1. If in doubt, consult Analogic Corporation or your local Analogic Corporation representative.

---

**WARNING**



It is the user's responsibility to ensure that the monitor and the user's defibrillator perform safely and effectively when connected.

---

**WARNING**



Improper operation can result in harm to the patient.

---

**WARNING**



Two or more medical electrical equipment devices connected to a patient at the same time can cause signal interference.

---

**WARNING**



It is not recommended that this device be used with any unauthorized consumable CO<sub>2</sub> sampling products which are not manufactured by Oridion Medical 1987 Ltd.

---

## 2.4

### Cautions

---

**Caution**



Do not connect this monitor to any other equipment or device other than those specified in this Operator's Manual.

---

**Caution**



Sterilization is not recommended for this monitor, related products, accessories or supplies unless otherwise indicated in the the instructions that accompany the accessories and supplies.

---

**Caution**



The LIFEGARD II may be used on a patient during defibrillation, but the readings may be inaccurate for <8 seconds per AAMI EC13-2002.

---

**Caution**



Use standard institutional procedures to dispose of used electrodes. Do not re-use.

---

**Caution**



To avoid obtaining monitored data for a wrong (or non-existent) patient, review the entered data for accuracy.

---

**Caution**



Whenever the Patient Data Menu is invoked, a new patient record is established in the monitor.

---

**Caution**



Do not immerse the monitor in liquid or use caustic or abrasive cleaners.

---

**Caution**



Do not spray or pour any liquid on the monitor or its accessories.

**Caution**

Anytime you press the Audio Alarm Control button, you should check the resulting state of the audio alarms indicated by the icons in the parameter frames to ensure that the alarm system is in the mode you expect.

**Caution**

Whenever you press the Audio Alarm Control button, ensure that the alarm system is in the desired mode of operation.

**Caution**

Do not allow any liquid to penetrate connectors or openings in the monitor's chassis.

**Caution**

After drying a wetted component (monitor, cable, sensor, etc.) obtain the assistance of qualified service personnel to assure safe operating condition.

**Caution**

To protect the monitor from damage during defibrillation, for accurate ECG information and to protect against noise and other interference, use only ECG electrodes and cables specified by Analogic.

**Caution**

Do not use disposable sensors in a high humidity environment, such as in the presence of fluids, which may contaminate sensor and electrical connections causing unreliable or intermittent measurements.

**Caution**

Extension Cables: Do not use more than one SpO<sub>2</sub> extension cable (10-64075-02).

**Caution**

Electrical Interference: Position the sensor cable and connector away from power cables to avoid electrical interference.

**Caution**

Do not use the SpO<sub>2</sub> ear transducer for patients with a small ear lobe as incorrect measurements may result.

**Caution**

If you measure SpO<sub>2</sub> on a limb that has an inflated NIBP cuff, the arterial blood isn't pulsing anymore and therefore, no new SpO<sub>2</sub> value and no pulse rate can be determined during that time. To prevent an SpO<sub>2</sub> INOP alarm in those cases, the monitor can detect this condition and suppress this alarm, but there may be a delay of up to 60 seconds in indicating critical patient status, such as sudden pulse loss of hypoxia.

**Caution**

Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities.

**Caution**



Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If the skin quality changes, or if the extremity circulation is being affected, move the cuff to another site or stop the blood pressure measurements immediately. Check more frequently when making automatic or STAT measurements.

---

**Caution**



A less severe NIBP artifact measurement may produce an NIBP measurement. The “NIBP Artifact” message displays and a low priority alarm tone sounds, but pressing the Audio alarm Control button clears the message and alarm tone.

---

**Caution**



If the values appear questionable, it is the clinician’s responsibility to repeat the measurements.

---

**Caution**



Trend records are not erased from the monitor’s memory when you power off. Be aware that when you power-cycle the monitor, existing trend records will not appear in the display, unless the Previous Trend Records option has been set to ‘Make Available.’ To change this display option, contact your biomed or other qualified service personnel.

---

**Caution**



When EtCO<sub>2</sub> is off and an ICG cable is connected, EtCO<sub>2</sub> will not be available until power ON/Standby is cycled.

---

**Caution**



Use only Analogic supplied paper. Using incorrect paper can result in damage to your recorder.

---



Figure 2-1. Explanation of Symbols























Symbol	Description
	Reference Number
	Serial Number
	CE MDD Marking
	Humidity Limits
	Temperature Limits
	Keep out of Sun
	Keep Dry
	Fragile
	Keep Upright
	AC LED
	Battery LED
	NIBP
	Artery Location for Cuff
	Volume
	Contrast
	On/Standby
	Snapshot
	Continuous
	Defibrillator-proof Type CF Equipment
	ECG
	Audio Alarm Control Button
<b>T</b>	Temperature
<b>SpO<sub>2</sub></b>	SpO <sub>2</sub>
	NIBP
<b>EtCO<sub>2</sub></b>	End-Tidal Carbon Dioxide

Figure 2-1. Explanation of Symbols (continued)

















Symbol	Description
<b>CO</b>	Cardiac Output
<b>CI</b>	Cardiac Index
<b>SVR</b>	Systemic Vascular Resistance
<b>SVRI</b>	Systemic Vascular Resistance Index
<b>TFC</b>	Thoracic Fluid Content
<b>ACI</b>	Acceleration Index
<b>SV</b>	Stroke Volume
<b>SI</b>	Stroke Index
	Alarm Label
	AC LED
	Audio Off
	NIBP Automatic Interval Mode
	Large Numbers
	Clock
	Up Alarm Arrow Limit
	Down Alarm Arrow Limit
	Battery Status Icon
	SpO <sub>2</sub> Perfusion Indicator Bar
	ICG Signal Quality Indicator
	Heart Rate
	Entering Stand-by. Please wait.
	Heart Rate taken from ECG
	Heart Rate taken from NIBP
	Electrostatic sensitive

Figure 2-1. Explanation of Symbols (continued)

























Symbol	Description
	Heart Rate taken from SpO <sub>2</sub>
	Respiration from impedance (ECG)
aw RR	Respiration from EtCO <sub>2</sub>
	Stat Mode
	Audio Pause
	Setup Menu
	ECG/VECG/ICG Size Bar
	RF Interference
	Battery Compartment
	RS-232 I/O
	Equipotential Grounding Post
	Attention, Consult Accompanying Documents
	Alternating Current
 T1AL 250V	Fuse Type
 YYYY-XX	Date of Manufacture (Y = year; X = Month)
IPX1	Drip-proof
	ETL Mark
RXOnly	This device restricted to sale by or on the order of a physician
	Single Patient Use Only
	Latex-free
	Manufacturing Lot
	Use by date (yyyy mm)
 7d MAX	Use within 7 days of opening package
	USB Host Connector

Figure 2-1. Explanation of Symbols (continued)

Symbol	Description
	Shave hair from sites, if necessary
	Wash sites with soap and water
	Dry sites briskly

# Site Preparations

## 3.1 General

This chapter describes site preparation procedures and guidelines to ensure compliance with safety requirements.

## 3.2 General Site Preparation Safety Information

---

**WARNING**

To avoid contaminating or infecting personnel, the service environment or other equipment, make sure that equipment which has been used before has been appropriately disinfected and decontaminated.

---

**WARNING**

Disconnect the monitor from the AC source by unplugging the power cable from the AC power connector located on the rear of the monitor. The On/Standby button does not disconnect the monitor from the AC mains supply.

---

**WARNING**

Accessory equipment connected to the monitor's data interface must be certified according to IEC Standard 60950 for data-processing equipment or IEC Standard 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 system requirements.

---

**WARNING**

Explosion Hazard. Equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.

---

**WARNING**

Be sure you have read all applicable instructions before attempting to install the wall mount.

---

**WARNING**

Wall mounts that are intended to support monitors must be capable of supporting 4 times the weight of the monitor when properly installed.

---

**WARNING**

Do not mount any portion of a monitoring instrument over a patient's bed.

---

**WARNING**

Do not exceed the maximum rated load specified for each wall mount.

---

**WARNING**

Ensure that no electrical wiring, utilities, or piping interfere with the selected wall mounting locations.

---

### 3.3 **Site Preparation Guidelines**

- Check that the environment is reasonably free from dust, vibration, corrosive or explosive gases and is within specified temperature and humidity ranges. See Chapter 13, *Specifications*.
- Position the monitor so that the display is clearly visible and the controls are easy to reach.

### 3.4 **Safety Precautions**

#### **Patient Safety**

To better ensure patient safety, become familiar with the details in Chapter 13, *Specifications*.

#### **Patient Leakage Current**

The patient leakage current is  $\leq 50 \mu\text{A}$  @ 250V. The monitor has patient input connectors (Type CF) that are protected against the effects of defibrillation and electrosurgery.

The following heart symbol is located on the side of the monitor where the patient monitoring input connectors are. The symbol indicates that the monitor is Type CF and is designed to have special protection against electric shocks (particularly regarding allowable leakage current, having an F-Type applied part, according to the standards IEC 60601-1/EN60601-1/CSAC22.2 601.1/UL 2601-1), and is defibrillator proof.



### 3.5 **Preparing to Use the Monitor**

---

#### **WARNING**



To avoid contaminating or infecting personnel, the service environment or other equipment, make sure that equipment which has been used before has been appropriately disinfected and decontaminated.

---

#### **Power Source Requirements**

See the section entitled, *Electrical* in Chapter 13, *Specifications* for all electrical specifications.

#### **Protecting Against Electrical Shock**

The LIFEGARD II patient monitor is classified as Class I Equipment with an internal power source in accordance with IEC 60601-1/CSAC22.2 601.1/UL 2601-1. The monitor has grounding contacts in the power plug, ensuring that all exposed conductive surfaces are at the same electrical potential as the surface of the Earth, to avoid the risk of electrical shock if a person touches a device in which an insulation fault has occurred.

---

#### **WARNING**



Disconnect the monitor from the AC source by unplugging the power cable from the AC power connector located on the rear of the monitor. The On/Standby button does not disconnect the monitor from the AC mains supply.

---

### ***Equipotential Grounding***

To eliminate potential differences between different pieces of equipment, the monitor must have a separate connection to the equipotential grounding system.

One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding post on the rear of the monitor, and the other end is connected to one point of the equipotential grounding system.

### ***Combining Equipment***

All combinations of medical equipment with non-medical equipment must comply with IEC 60601-1-1.

---

#### **WARNING**



Accessory equipment connected to the monitor's data interface must be certified according to IEC Standard 60950 for data-processing equipment or IEC Standard 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1-1 system requirements.

## **3.6 Monitor Disposal**

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the monitor appropriately before disposing of it in accordance with your country's law for equipment containing electrical and electronic parts.

For disposal of parts and accessories, such as ECG and SpO<sub>2</sub>, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

For disposal of the lead-acid battery, follow local regulations for safe disposal of lead.

---

#### **WARNING**



Explosion Hazard. Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.

## **3.7 Unpacking the Monitor**

The box comes with the following:

- The LIFEGARD II Operator's Manual
- The LIFEGARD II patient monitor
- An AC power cord

In addition, you should receive all the accessories and options that you ordered.

If there is anything missing, contact your Analogic Corporation representative immediately.

## **3.8 Checking the Shipment**

Examine the carton carefully for evidence of damage in transit. If any damage is discovered, contact the carrier immediately. Retain all packing material.

If the monitor has to be returned, contact your Life Care Systems Support Group representative for shipping instructions.

To pack the monitor for return, disconnect all cable. Pack the monitor in its original shipping carton. If this is unavailable, use a suitable carton with appropriate packing material to protect the monitor during shipping.

---

**NOTE**

When returning the monitor for servicing, do not return sensors, patient cables, NIBP tubing and cuff, or the power cord.

---

### **3.9      *Returning System Components***

If it is necessary to return the monitor for service, call Analogic Corporation for shipping instructions. Have all equipment serial numbers available when calling.

To pack the monitor for return, disconnect all cables. It is not necessary to return sensors, patient cables, NIBP tubing and cuff or power cord. Pack the monitor to be returned in its original shipping carton if available. If not, use a suitable carton with appropriate packing material to protect the monitor during shipping.



# Maintaining the Monitor

## 4.1 General

This chapter describes how to clean the LIFEGARD II patient monitor and keep it in the best working condition.

## 4.2 Maintenance Safety Information

---

### WARNING



Follow local governing ordinances and recycling plans regarding disposal or recycling batteries and other device components.

---

### WARNING



If the battery shows signs of damage or signs of leakage, replace it immediately. Do not use a faulty battery in the monitor.

---

### Caution



Do not immerse the monitor in liquid or use caustic or abrasive cleaners.

---

### Caution



Do not spray or pour any liquid on the monitor or its accessories.

---

### Caution



Do not allow any liquid to penetrate connectors or openings in the monitor's chassis.

---

## 4.3 Objectives

In order to meet this chapter's objectives, you should be able to perform light maintenance and preventive maintenance for the monitor through the following tasks:

- Inspection of the monitor
- Cleaning of the monitor
- Battery Maintenance

## 4.4 Concepts

### **Light Maintenance**

Light maintenance tasks can be defined as those tasks required to maintain the monitor in clean, functional working order. These include inspection, cleaning practice and battery maintenance as well as the continuous observation of replaceable parts for wear.

## 4.5 **Recommendations for Maintenance Frequency**

The following table is the recommended maintenance schedule for the LIFEGARD II patient monitor. The maintenance checklist appears in the next section of this chapter. The checklist may be photocopied and should be completed by the maintainer. It should be filed for future reference. The owner of the equipment is responsible for the performance of the maintenance activities with the schedule below.

<b>Maintenance</b>	<b>Frequency</b>	<b>Procedure</b>
Inspect the monitor, cables and cords	Daily	<i>"Inspecting the Monitor"</i> on page 4-3 and <i>"Inspecting the Cables and Cords"</i> on page 4-3
Cleaning	As needed	<i>"Cleaning"</i> on page 4-3
Safety checks according to IEC 60601-1	At least once every 2 years, after any repairs, if the monitor has been dropped, or as needed.	<i>"Patient Safety Tests"</i> on page 5-25
Functional testing procedures	When functional defects in the measurements are suspected.	<i>"Functionality Assurance"</i> on page 5-3
Performance Assurance	At least once every year, or as needed (if you suspect defects in the measurements).	<i>"Performance Assurance Test"</i> on page 5-7
Replace backlight	20,000 hours (about 4 years) of continuous use, or as needed.	<i>"Replacing the Backlight Tube"</i> on page 8-6
NIBP Maintenance	Every year, or as needed, if the monitor has been opened, or you suspect defects in the measurement.	<i>"Preventive Maintenance Tests"</i> on page 5-9
Battery Maintenance	Every two years	<i>"Battery Maintenance"</i> on page 4-4

### **Maintenance Checklist**

<b>Topics</b>	<b>See Page...</b>
Inspect Cables, Cords and Housing	4-3
Cleaning Guidelines	4-3
Checking the Battery Status	4-5
Charging the Battery	4-5
Testing the Monitor	5-1
NIBP Preventive Maintenance	5-9
Replacing the Backlight Tube Assembly	8-6

### ***Inspecting the Monitor***

If a problem is discovered while inspecting the LIFEGARD II patient monitor, contact your biomedical department or the Life Care Systems Support Group.

With the monitor in Standby and mains removed:

Step	Action
1	Examine the exterior of the monitor for cleanliness and general physical condition. Verify that the housing is not cracked or broken, that everything is present, that there are no spilled liquids and that there are no signs of abuse.
2	Inspect all accessories (cables and sensors) external to the monitor, referring to the accessories' documentation.
3	Switch the monitor On and verify that the backlight is bright enough. Check that screen is at its full brightness. If the brightness is not adequate, contact your biomedical department. The Life Care Systems Support Group recommends replacing the backlight about every 4 years.
4	If you are operating the monitor from battery, verify that the battery is adequately charged before you begin use.

### ***Inspecting the Cables and Cords***

If a problem is discovered while inspecting the cables and cords, replace the cable, or contact your biomedical department.

Step	Action
1	Examine the power plug and cord for damage. Make sure that the prongs of the plug do not move in the casing. If damaged, replace the entire cord with the appropriate Analogic power cord. (See spare parts, Section 19 of Operator's Manual.
2	Inspect the patient cables and leads and their strain reliefs for general condition. Make sure there are no breaks in the insulation. Make sure that the connectors are properly engaged at each end to prevent rotation or other strain.
3	With the sensor or electrodes applied to the simulators (see Section 5), and the monitor turned On, flex the patient cables near each end to make sure that there are no intermittent faults.

## **4.6 Cleaning**

### ***Caution***



Do not immerse the monitor in liquid or use caustic or abrasive cleaners.

### ***Caution***



Do not spray or pour any liquid on the monitor or its accessories.

### ***Caution***



Do not allow any liquid to penetrate connectors or openings in the monitor's chassis.

To clean the monitor, dampen a cloth with a commercial, nonabrasive cleaner and wipe the top, bottom, and front surfaces lightly. For cables, sensors and cuffs, follow the cleaning instructions in the Directions for Use shipped with those components.

If liquid is spilled on the monitor, remove the monitor from mains, clean and dry it thoroughly before use.

If in doubt about monitor safety, refer the unit to qualified service personnel.

## 4.7 **Battery Maintenance**

This section provides information on how to handle and maintain the battery.

---

### **WARNING**



Follow local governing ordinances and recycling plans regarding disposal or recycling batteries and other device components.

---

#### **About the Battery**

Storing the monitor for a long period of time without charging the battery can degrade the battery capacity. A complete battery recharge (>90%) requires 8 hours in standby mode or 14 hours in operational mode. If the battery needs charging, connect the monitor to the AC outlet as described in “*Charging the Battery*” on page 4-5.

If the monitor then operates for less than one hour on battery power before the low battery alarm occurs, the battery should be replaced. See “*Electrical*” in Chapter 13 for typical battery operating times and conditions and see “*Removing the Battery*” on page 8-2 for more information.

#### **Battery Guidelines**

To get the most out of the battery, observe the following guidelines:

- The shelf-life of a fully charged battery is about 6 months.
- After a battery has been activated, keep it charged. If it is not in use, recharge it every 3 to 4 months.
- If the monitor is not in use for long periods of time, greater than 3 months, remove the battery from the monitor. (Leaving the battery in a monitor that is not regularly using the battery will shorten the life of the battery.)
- Battery Disposal – We recommend replacing the monitor’s sealed, lead-acid battery at 2-year intervals. Follow local governing ordinances and recycling plans regarding disposal or recycling of batteries and other device components.
- Do not dispose of the battery in normal waste containers.

---

### **WARNING**



If the battery shows signs of damage or signs of leakage, replace it immediately. Do not use a faulty battery in the monitor.

---

### ***Checking the Battery Status***

When the monitor is connected to the AC (mains) power supply, the battery charges automatically.

Battery status is indicated several ways:

- LEDs on the front panel of the monitor.
- Battery gauge on the monitor's main monitoring screen
- INOP messages

The AC LED is only on when the power cord is connected and the AC power is available to the monitor. In this case, the battery is either charging or is fully charged.

### ***Identifying Battery Strength***

Battery strength can be determined by the color of the battery icon or by the number of illuminated bars on the battery icon. The following table describes the battery icon behavior.

Number of Bars Illuminated	Color Used	Behavior	Status
3, 4, or 5	Green	Constant display	OK for service
2	Yellow	Constant display	Finish session. Do not begin new session.
1	Red	Constant display	Pull out of service for charging
0	Red	Battery icon flashes and message displays	Pull out of service. Charge immediately.

- If the battery operating time is less than 30 minutes, the battery icon flashes. A low priority audio alarm sounds (1 beep every 4 seconds).
- When the battery is empty, a "Low Battery" INOP message displays in the Message frame and the audible alarm sounds. Pressing any front panel button clears the INOP and silences the audible alarm. The battery icon continues to flash until the monitor is powered down or automatically switches off and the monitor will sound the loss of monitoring alarm.

### ***Charging the Battery***

A complete battery recharge (>90%) requires 8 hours in standby mode or 14 hours in operational mode.

To charge the battery:

Step	Action
1	Connect the monitor to the AC power source using the proper power cord.
2	Verify that the AC Input Indicator LED is lit.
3	Charge the battery for at least 8 hours. The battery may require a full discharge/charge cycle to restore it to its normal capacity.
4	To check for a full charge, perform the procedure described in "Battery Performance Test" on page 5-14.

### ***Battery INOP Messages***

The following battery-related INOP message is issued by the monitor. The Battery INOP will continue until the monitor is plugged into the AC power or the INOP condition is fixed.

- “Low Battery” — This is an INOP which indicates that the remaining battery-operating time is less than approximately 30 minutes.

# Configuring the Power-up Defaults Menu

This chapter discusses the use of the Power-up Defaults Menu to configure power-on default settings. It also explains how to use Diagnostic Mode to obtain service-related information about the monitor.

## 5.1 General Safety Information

---

### WARNING



A blood pressure cuff, connected to the monitor, should never be applied to a human being while the monitor is in Diagnostic Mode. Injury could result.

A FilterLine, connected to the monitor, should never be applied to a human being while the monitor is in Diagnostic Mode. Injury could result.

---

### Caution



In addition to restoring factory defaults, this procedure clears the contents of trend memory.

---

### NOTE

Before performing the first step, read this procedure COMPLETELY.

---

## 5.2 Power-up Defaults Menu

The purpose of the Power-up Defaults Menu is to allow the authorized user to create a power-up default for each setting in the monitor. Power-up defaults are the settings in effect each time the monitor is powered on. Upon entering the Power-up Defaults Menu, physiological monitoring is terminated. The screen layouts do not display any information associated with normal monitoring operation.

After configuring the main monitoring screen and connecting the appropriate accessories, use the following procedure to configure the power-up default settings for the monitor.

Step	Action
1	From the main monitoring screen, use the navigation wheel to highlight the <b>Setup</b> icon. Press the wheel to select the icon.
2	From the <b>Setup Menu</b> , select <b>Enter Power-up Default Menu</b> . A popup box displays.
3	Use the wheel to enter the passcode: <b>2 1 5</b> <b>Note:</b> This passcode is configured at the factory and CANNOT be changed.
4	<div>The <b>Power-Up Defaults Menu</b> displays. (Factory defaults are shown in parenthesis.)<div><div><b>POWER-UP DEFAULT MENU</b></div><div>Accept Current Settings? Selected Audio Off (Make Available) Audio Off (Make Available) Auto-Set Limits (Make Available) Audio Pause Period (180s) Enter Diagnostic Mode? Language (English) Enter Demo Mode? Patient Data Units (Metric) Previous Trend Data (Deny Access) Low Priority Alarm Interval (4s or 15s) Return</div></div><div>The available menu items are described in the next section. These menus can be configured as desired.</div></div>
5	After making the desired change, highlight <b>"Accept Current Settings?"</b> Press the wheel to select this option.
6	From the popup menu, select <b>Yes</b> .
7	Select <b>Return</b> .  After selecting <b>Return</b> , a notice displays instructing you to power down the monitor. Next time you power on, the changes you made to the defaults are implemented.



### Menu Options

Below are the menu options that can be configured from the Power-up Defaults Menu.

Menu Item	Choices	Explanation
Accept Current Settings	Yes No	If <b>Yes</b> is chosen, the current monitor settings become the power-up defaults.
Selected Audio Off	Make Available (default) Deny Access	If <b>Make Available</b> is chosen, audible alarms are permanently silenced for a particular parameter via the <b>Alarm Limits Menu</b> .  Some institutions may want to prevent audible alarms from being permanently silenced. If so, select <b>Deny Access</b> .
Audio Off	Make Available (default) Deny Access	If <b>Make Available</b> is chosen, Alarm Suspend Mode can be invoked by pressing and holding the <b>Alarm Silence</b> button for 2 seconds.  Some institutions may wish to prevent Alarm Suspend from being invoked. If so, select <b>Deny Access</b> .
Auto-Set Limits	Make Available (default) Deny Access	If <b>Make Available</b> is chosen, Auto-Set Limits are invoked via the <b>Alarm/Limits Menu</b> .  Some institutions may wish to prevent Auto-Set Limits from being invoked. If so, select <b>Deny Access</b> .
Audio Pause Period	30, 60, 90, 120 (default), 180s	Time is indicated in seconds. Pressing the front panel <b>Alarm Silence</b> button temporarily silences audible alarms for the time indicated.
Enter Diagnostic Mode	Yes No	If <b>Yes</b> is chosen, the <b>Power-up Defaults Menu</b> is exited and the <b>Diagnostic Menu</b> displays. For more information, see <i>Diagnostic Mode</i> on page 5-4.
Language <sup>a</sup>	English, French, German, Italian, Japanese, Portuguese, Spanish, Russian, Chinese, Dutch, Turkish, Arabic, Norwegian, Swedish, Finnish, Polish, Czech, Danish or Greek	All text shown on the screen is in the selected language. The selected language is effective the next time the monitor is powered up.
Enter Demo Mode?	Yes No	If <b>Yes</b> is chosen, the monitor simulates patient inputs. For more information see <i>Demo Mode</i> on page 5-10.
Patient Data Units	U.S. Metric (default)	This selection controls the engineering units for patient weight and height used in ICG mode. (AN4321P and AN4323P)
Previous Trend Data	Make Available Deny Access (default)	If <b>Make Available</b> is chosen, all stored trend data from all records can be viewed. The default allows only the current patient record to be viewed.
Low Priority Alarm Interval	4s (default) 15s	This defines the repetitive interval of the two beeps.
Return		When selected, the <b>Power-up Defaults Menu</b> is immediately exited and you are instructed to power down the monitor.

*a. Although the language choices are shown here in English, they display on the screen in their respective language and script on the Boot Up screen and in the **Power-up Defaults Menu**.*

### Diagnostic Mode

The purpose of the Diagnostic Mode Menu option is to allow factory, field-service, and hospital biomedical technicians access to a series of test and system-related information screens for the purpose of verifying monitor performance, or troubleshooting problems.

To access Diagnostic Mode:

Step	Action
1	Enter the <b>Power-up Defaults Menu</b> (see <i>Power-up Defaults Menu</i> on page 5-2 for instructions on accessing this menu).
2	Select the <b>Enter Diagnostic Mode?</b> option.
3	From the popup menu, select <b>Yes</b> . The <b>Diagnostic Menu</b> displays. <div><div><b>DIAGNOSTIC MENU</b></div><div>Error Codes System Information System A/D Values NIBP Test CO<sub>2</sub> Test (AN4322P and AN4323P models)  Return</div></div>

The **Diagnostic Menu** lists the test and system-related information screens. Select an item in the menu to invoke a test or information screen. The test and information screens that are in the diagnostic menu are listed below. An explanation of each menu is given in the sections that follow.

- Error Codes
- System Information
- System A/D Values
- NIBP Test
- CO<sub>2</sub> Test (AN4322P and AN4323P models)

When entering **Return** in the **Diagnostic Menu**, the operator is prompted to turn off the monitor to save any changes that were made.

**Error Codes**

DIAGNOSTIC MENU	
ERROR CODES	
Error Codes	Date/Time
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
Return	

This screen displays the 10 most recent error code types, logged by the monitor. The date and time that the error code appeared displays to the right of the error code.

Error codes cannot be changed or reset in this screen. When in the Error Code screen, the **Return** option is always highlighted. Press the wheel to return to the Diagnostic menu. Rotating the navigation wheel while in the Error Code screen has no effect.

Refer to *Error Code Categories* on page 7-9 for more details on error codes.

**System Information**

DIAGNOSTIC MENU	
SYSTEM INFORMATION	
Monitor On-Time	0
Backlight On-Time	0
Recorder On-Time	0
Battery Deep Discharges	0
System Software Version	Application VX.XX
CO <sub>2</sub> Software Version	00.01 NL V01.11 09/05/2000 SN 10971
SpO <sub>2</sub> Software Version	NELLCOR MP100 1.4.0.0 03/08/04
NIBP Software Version	LM3. 386 SM V219 a
	123456      Cycle 369
Return	

When in the System Information screen, the wheel can be rotated to select any of the changeable items. If one of those items is selected, a press of the wheel displays a popup menu. The first item is **Make No Change**; the second item is **Reset to Zero**.

This screen displays several system-related items. They are as follows:

Menu Item	Function
Monitor On-Time	Displays the number of hours, rounded to the nearest hour, that the Main PCB has been operational. This value CANNOT be reset.
Backlight On-Time	Displays the number of hours, rounded to the nearest hour, that the LCD Backlight has been operational. This value can be reset to zero. An example is when a technician changes the backlight or installs a new LCD.
Recorder On-Time	Displays the number of hours, rounded to the nearest hour, that the recorder has been operational. This value can be reset to zero. An example is when a technician installs a new recorder.
Battery Deep Discharges	Displays the number of deep-discharge cycles seen by the battery. When this point is reached, a <b>Low Battery</b> alarm is issued. This value can be reset to zero. An example is when a technician installs a new battery.
System Software Version	Displays the revision level of the system software. The revision level is also momentarily shown on the LCD as part of the copyright screen. The value CANNOT be changed.
CO <sub>2</sub> Software Version	Displays the revision level of the software of the Oridion® CO <sub>2</sub> module. This value CANNOT be changed.
SpO <sub>2</sub> Software Version	Displays the revision level of the software of the MP-100 SpO <sub>2</sub> module. This value CANNOT be changed.
NIBP Software Version	Displays the revision level of the software for the NIBP module. This value CANNOT be changed.
Return	Exits the <b>System Information Menu</b> and returns to the <b>Diagnostic Menu</b> .

### System A/D Values

The System A/D screen displays the current value of each analog-to-digital (A/D) channel in volts. Some of the channels are for AC-coupled signals (such as ECG input), so the numbers on the screen are constantly changing when an input signal is present. These AC-coupled values are shown to give an indication as to whether basic functionality of the channel is present, but no significance can be derived from the values of the numbers displayed.

DIAGNOSTIC MENU				
SYSTEM A/D VALUES				
1.	0.000	12.	2.025	
2.	3.270	13.	0.000	
3.	2.495	14.	0.000	
4.	2.275	15.	1.815	
5.	0.000	16.	2.782	
6.	3.280	17.	0.007	
7.	2.048	18.	4.050	
8.	0.000	19.	0.003	
9.	0.000	20.	3.995	
10.	2.048	21.	2.004	
11.	2.048	22.	4.049	
		23.	4.051	
SpO <sub>2</sub> S1	SpO <sub>2</sub> Alive	SpO <sub>2</sub> S2	No Sensor	
Return				

The Primary and Secondary Status messages from the SpO<sub>2</sub> module are displayed and updated at the rate of about once per second. Presence of the correct SpO<sub>2</sub> message indicates that, at a basic level, communication between the SpO<sub>2</sub> module and the main monitor processor is working correctly. None of the displayed values can be changed or reset in this screen. When in the System A/D screen, the **Return** option is always highlighted. Press the wheel to return to the **Diagnostic menu**. Rotating the wheel while in the System A/D screen has no effect.

### **NIBP Test**

A NIBP Test screen is provided to facilitate troubleshooting problems and performing verification testing for the NIBP subsystem. Typically, when these tests are performed, the pneumatic system is connected to an external pressure-reading device and a closed reference volume. The NIBP Test screen provides a real-time numeric display of the pressure in the pneumatic system, means for controlling the pump and valves are open or closed.

### **WARNING**



A blood pressure cuff, connected to the monitor, should never be applied to a human being while the monitor is in Diagnostic Mode. Injury could result.

DIAGNOSTIC MENU	
NIBP TEST	
Pressure (mmHg) 0	Proportional Valve: Open Safety Valve: Open
Press NIBP to activate pump; release to stop pump.	
Press Volume to open both valves; release to close valve.	
Press Alarm Silence to open proportional valve and deflate at 3 mmHg/s; release to close valve	
Press Contrast to perform offset adjustment	
Return	

The NIBP Test screen elements are described below:

Menu Item	Function
Pressure (mmHg)	Displays the real-time value of the system pneumatic pressure in mmHg. The value is updated at the rate of approximately two times per second.
Proportional Valve	Indicates whether the proportional valve is open or closed.
Safety Valve	Indicates whether the safety valve is open or closed.
Activate Pump	As long as the <b>NIBP</b> button is pressed, the pump runs. If system pressure reaches the hardware over-pressure protection point (280 to 330 mmHg or 37.3 to 44.0 kPa), the safety valve opens and the pump disables, until the pressure falls below the safety threshold.
Open Both Valves	As long as the <b>Volume</b> button is pressed, the safety valve and proportional valve opens and remains at maximum.
Deflate	As long as the <b>Alarm Silence</b> button is pressed, the proportional valve opens and bleeds off pressure at the rate of $3 \pm 1.5$ mmHg/s. It is useful to control the bleed rate to 3 mmHg/s to facilitate certain AAMI SP10 tests. Any time the bleed rate falls below 3 mmHg/s, the valve opens and remains at maximum as long as the button is pressed.
Offset Adjustment	Momentarily pressing the <b>Contrast Adjust</b> button invokes the Zero Calibration routine that is performed immediately prior to each blood pressure measurement. This routine looks at the pressure in the system and if the pressure is non-zero, an offset is applied which causes the system pressure to display as Zero.

When in the NIBP Test screen, the **Return** option is always highlighted. Press the wheel to return to the **Diagnostic Menu**. Rotating the wheel while in the NIBP Test screen has no effect.

### **CO<sub>2</sub> Test**

The CO<sub>2</sub> Test Screen is provided to facilitate troubleshooting problems and performing verification testing to ensure the measuring results are accurate. See *CO<sub>2</sub> Performance* on page 6-19 for information on how to perform these tests.

### **WARNING**



A FilterLine, connected to the monitor, should never be applied to a human being while the monitor is in Diagnostic Mode. Injury could result.

DIAGNOSTIC MENU	
CO <sub>2</sub> TEST	
CO <sub>2</sub> Pressure in mmHg (ambient/cell):	745/740
Pump Voltage (Volts):	3.0
CO <sub>2</sub> (mmHg):	0.00
Status:	
Set Barometric Pressure (mmHg):	745
Flow Rate Check and Calibration:	
CO <sub>2</sub> Calibration:	07/16/2005 15:13
Pump Op Time:	58
Return	

The CO<sub>2</sub> Test Screen is described below:

Menu Item	Function
CO <sub>2</sub> Pressure in mmHg (ambient/cell)	Displays the real-time value of the ambient pressure and the measured cell pressure. The ambient pressure value will be the same as the Barometric Pressure value. This value CANNOT be changed or reset.
Pump Voltage (Volts)	Takes the correct amount of air from outside of the monitor. This value CANNOT be changed or reset.
CO <sub>2</sub> (mmHg)	Displays the real-time value of CO <sub>2</sub> . This value CANNOT be changed or reset.
Set Barometric Pressure (mmHg)	Select a value which matches the reference value received from a reliable source (airport, weather station, hospital). Confirm that the ambient pressure value is the same as the barometric pressure value.
Flow Rate Check and Calibration	Adjust CO <sub>2</sub> flow rate by <b>Decrease Flow</b> or <b>Increase Flow</b> . After desired flow rate is obtained, select <b>Store Flow</b> . Highlight and press <b>Return</b> to exit popup menu.
CO <sub>2</sub> Calibration	Displays the date and time that the last calibration occurred.  To calibrate CO <sub>2</sub> , you must follow the procedure outlined on page 5-22.
Pump Op Time	Displays the length of time that the pump has been operational. A " <b>CO<sub>2</sub> Calibration Required</b> " message will appear in the message frame after the first 1,200 hours of operation or after 12 months, whichever comes first. Thereafter it will occur every 4,000 hours of operation or after 12 months, whichever comes first. (See CO <sub>2</sub> Gas Measurement Calibration Check in Section 5.) After 20,000 hours of operation, the monitor <b>MUST BE RETURNED</b> to the factory for maintenance. Pump Op Time can only be reset to Zero at the factory and only after required maintenance.
Return	Exits the <b>CO<sub>2</sub> Test</b> and returns to the <b>Diagnostic Menu</b> .

## Restoring Factory Settings

### Caution



In addition to restoring factory defaults, this procedure clears the contents of trend memory.

The following technique can be used to restore the monitor's power-up default setting which were originally configured in the factory.

### NOTE

Before performing the first step, read this procedure **COMPLETELY**.

Step	Action																				
1	Ensure that the monitor is powered Off.																				
2	Simultaneously press the <b>Volume</b> and <b>Contrast</b> buttons on the monitor's front panel.																				
3	Still pressing the <b>Volume</b> and <b>Contrast</b> buttons, press the On/Standby button to turn the monitor On.																				
4	Continue to press the <b>Volume</b> and <b>Contrast</b> buttons until the power-up diagnostic sequence is complete. When the main monitoring screen displays, release the two buttons.																				
5	<p>Select your language from the following screen, then select <b>Yes</b> to place the monitor into that language. After language is selected, the main monitoring screen displays.</p> <table border="1"> <tbody> <tr> <td>English</td><td>Dutch</td></tr> <tr> <td>Chinese</td><td>Turkish</td></tr> <tr> <td>French</td><td>Norwegian</td></tr> <tr> <td>German</td><td>Swedish</td></tr> <tr> <td>Italian</td><td>Finnish</td></tr> <tr> <td>Japanese</td><td>Polish</td></tr> <tr> <td>Portuguese</td><td>Czech</td></tr> <tr> <td>Spanish</td><td>Danish</td></tr> <tr> <td>Russian</td><td>Greek</td></tr> <tr> <td>English</td><td>? Yes</td></tr> </tbody> </table>	English	Dutch	Chinese	Turkish	French	Norwegian	German	Swedish	Italian	Finnish	Japanese	Polish	Portuguese	Czech	Spanish	Danish	Russian	Greek	English	? Yes
English	Dutch																				
Chinese	Turkish																				
French	Norwegian																				
German	Swedish																				
Italian	Finnish																				
Japanese	Polish																				
Portuguese	Czech																				
Spanish	Danish																				
Russian	Greek																				
English	? Yes																				

### Demo Mode

The simulation of patient data in the **Demo Mode** is to verify functionality of the various circuits without the use of sensors or a patient. It is also used as a convenient training tool.

While in Demo Mode, the message \* \* \* **DEMO** \* \* \* is displayed in the Message frame. To exit **Demo Mode**, power cycle the monitor from Power On to Standby and back to Power On.

### WARNING



While in Demo Mode, real patient monitoring ceases operation. All displayed patient data is simulated.

### NOTE

Demo mode is not 100% conclusive proof that the monitor is functioning. Although much of the internal circuitry is tested, the patient input circuits are not.



# Testing the Monitor

## 6.1 *General*

This chapter provides a checklist of testing procedures used to verify performance following repairs or during routine maintenance. All tests can be performed without disassembling the monitor.

If the monitor fails to perform as specified in any test, repairs must be done to correct the problem before the monitor is returned to the user.

## 6.2 *Testing Safety Information*

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### **WARNING**



Perform all leakage tests any time the unit is opened. AC mains voltage is present on the applied part terminals during this test. Exercise caution to avoid electrical shock hazard

---

## 6.3 *Objectives*

### ***Functionality Assurance***

This refers to the combined Performance Assurance Test and Functionality Testing Procedures found in this chapter. These tests verify correct monitor functionality in general terms.

### ***Preventive Maintenance***

Preventive Maintenance refers specifically to the service calibration tests required to ensure the monitor measurement results are accurate.

### ***Performance and Safety Tests***

This refers to all the remaining accuracy and performance tests available on the monitor, including safety tests and checks for the monitor.

## 6.4 *Testing Checklist*

The tests described in this chapter are listed in the table below. Use this table as a checklist.

Topics	See Page...	Check If Completed	Date Completed
<b>Functionality Assurance Tests</b>			
Functionality Assurance Test	6-7		
Power-On Self-Test	6-7		
Alarm Test	6-8		
Volume Control Test	6-9		
<b>Preventive Maintenance Tests</b>			
NIBP	6-9		
<b>Performance procedures</b>			
Battery Performance Procedures	6-14		
Temperature Test	6-16		
ECG Performance	6-16		
Respiration Performance	6-17		
SpO <sub>2</sub> Performance	6-18		
CO <sub>2</sub> Performance	6-19		
Serial Interface and Nurse Call Signal Test	6-24		
<b>Patient Safety Tests</b>			
S(1) Ground Integrity	6-25		
S(2) Electrical Leakage	6-26		
S(3) Earth Leakage Current	6-26		
S(4) Enclosure Leakage Current	6-27		
S(5) Patient Leakage Current	6-27		
S(6) Patient Leakage Current with Mains	6-28		

## 6.5 **Recommendations for Testing Frequency**

Perform the procedure as indicated in the suggested testing timetable. These timetable recommendations do not supersede local requirements. (See Testing Checklist, paragraph 6.4.)

---

### **NOTE**

All performance tests should be performed with a fully-charged battery.

---

<b>Suggested Testing</b>	<b>Frequency</b>
Functionality Assurance <ul style="list-style-type: none"> <li>• Performance Assurance Test</li> <li>• Power-On Self-Test</li> </ul>	When functional defects in the measurements are suspected, after any repairs, if the monitor has been dropped or opened.
Preventative Maintenance Tests (NIBP)	Every year, or as needed.
Performance Tests <ul style="list-style-type: none"> <li>• Battery Performance</li> <li>• Temperature Accuracy</li> <li>• ECG Performance</li> <li>• Resp Performance</li> <li>• SpO<sub>2</sub> Performance</li> <li>• CO<sub>2</sub> Performance</li> <li>• Serial Interface and Nurse Call Signal Test</li> </ul>	The battery performance test must be performed every two years, before monitor repairs, or whenever the battery is suspected as being the source of the problems.  All other tests must be performed at least once every year, if the monitor has been opened, or if you suspect defects in the measurements.
Safety Checks (in accordance with IEC 60601-1) <ul style="list-style-type: none"> <li>• Ground Integrity</li> <li>• Electrical Leakage</li> <li>• Earth Leakage Current</li> <li>• Enclosure Leakage Current</li> <li>• Patient Leakage Current</li> <li>• Patient Leakage Current with Mains Voltage on the Applied Part</li> </ul>	At least once every 2 years, after any repairs, if the monitor has been dropped or opened.

## 6.6 Test Map

The Test Map shows which tests are required in which situations.

Service Event (When performing...)	Test Block Required (...complete these tests)
Installation	<ul style="list-style-type: none"> <li>• Visual</li> <li>• Power On</li> </ul>
Monitor opened	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Pneumatic Leakage Test</li> <li>• All Safety Tests</li> </ul>
Battery replacement	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Battery Performance</li> </ul>
Speaker replacement	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Pneumatic Leakage Test</li> <li>• All Safety Tests</li> </ul>
Backlight tube replacement	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Pneumatic Leakage Test</li> <li>• All Safety Tests</li> </ul>
NIBP pump replacement	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Pneumatic Leakage Test</li> <li>• All Safety Tests</li> <li>• Preventive Maintenance Tests</li> </ul>
SpO <sub>2</sub> module replacement	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Pneumatic Leakage Test</li> <li>• All Safety Tests</li> <li>• SpO<sub>2</sub> Test</li> </ul>
CO <sub>2</sub> module replacement	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Pneumatic Leakage Test</li> <li>• All Safety Tests</li> <li>• CO<sub>2</sub> Tests</li> </ul>
Power supply module replacement	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Pneumatic Leakage Test</li> <li>• Safety Tests</li> </ul>
Patient monitoring I/O module replacement	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Pneumatic Leakage Test</li> <li>• All Safety Tests</li> <li>• All Performance Tests</li> </ul>
Communications module replacement	<ul style="list-style-type: none"> <li>• Power On</li> <li>• Pneumatic Leakage Test</li> <li>• Safety Tests</li> </ul>

## 6.7 Equipment

The following table lists the recommended equipment and accessories required for performance verification.

Equipment	Description
Brass hose connector	Swagelok, 1/8" NPT to 1/8" male hose barb connector
Digital multimeter (DMM)	Fluke model 87 or equivalent
SpO <sub>2</sub> extension cable	10-64075-02
SpO <sub>2</sub> reusable sensor, adult finger	AN4K-AC001
ECG patient cable	10-64667-01 (ICU) or 10-64667-02 (OR)
ECG electrodes	AN4K-AC033
ECG lead sets	10-64669-01 (AAMI) or 10-64669-03 (IEC)
NIBP tubing	AN4K-AC019
NIBP reusable cuff, adult	AN4K-AC017
Pulse oximeter tester	Clinical Dynamics Corp - SmartSat simulator with Nellcor simulator cable
ECG simulator	Dynatech Nevada medSim 300 or equivalent
NIBP simulator	Bio-Tek BP Pump 2 or equivalent
Pressure indicator	Condec, Model DLR334, CABBA, or equivalent
Temperature simulator	MedSim 300 or equivalent
Respiration simulator	MedSim 300 or equivalent
Safety analyzer	Bio-Tek 601 Pro or equivalent
Stopwatch	Manual or electronic
Screwdriver	flathead and philips
Tweezers	any model
Electronic flowmeter	Sierra Instruments <sup>1</sup>
Cal 1 gas (5% CO <sub>2</sub> ), CO <sub>2</sub> Filter Line included	Scott Medical Products <sup>2</sup>

Note 1. The electronic flowmeter can be purchased from Sierra Instruments, [www.sierrainstruments.com/products](http://www.sierrainstruments.com/products), Model #822-13-OV1-PV1-V1 (CO<sub>2</sub>, GAS, 0–75 ml range) plus the Power Supply, Model #820-T5 (115 VAC input) or Model #820-T6 (230 VAC input).

Note 2. The calibration gas (5% CO<sub>2</sub>), can be purchased from Scott Medical Products, [www.scottmedicalgases.com](http://www.scottmedicalgases.com), part number 0304653ORFBD. This part number is a kit especially prepared for the Oridion EtCO<sub>2</sub> module. It includes a 10 liter canister of 5% CO<sub>2</sub> medical grade, calibrated gas, and all the required tubing and patient connector.

## 6.8 Serial Numbers

When recording test results, these are always associated with a particular monitor by means of the serial number. The serial number is 10 characters and is located on the back of the monitor.

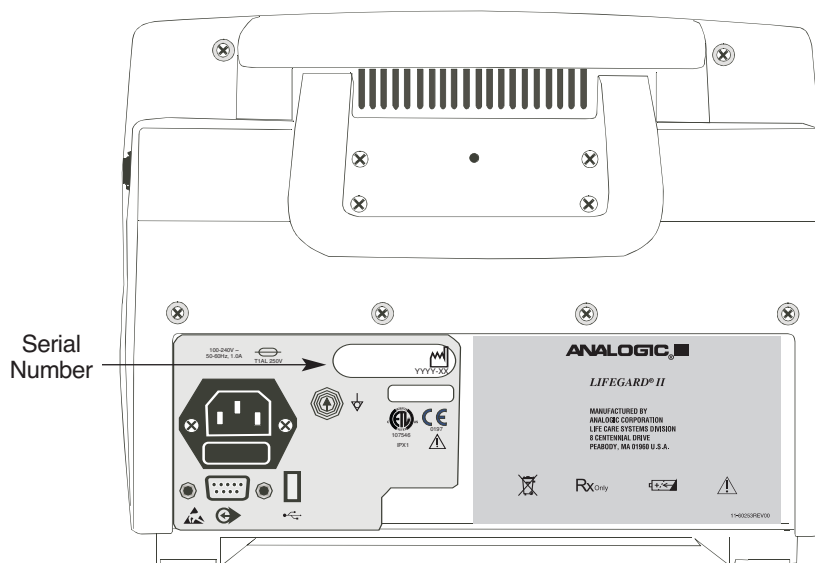


Figure 6-1. Serial Number Location.

## 6.9 Visual Test

Inspect the system for obvious signs of damage. Also check the external leads and accessories.

## 6.10 Passwords

Some of the tests may require that you enter the Power-Up Default Menu located in the Setup Menu. To access Power-Up Default Menu you must enter a password. The password is **2-1-5**.

## 6.11 **Functionality Assurance Tests**

The following assurance checks are recommended to verify proper operation daily before the monitor is used to monitor a patient.

During functionality assurance checks, verify the overall operation by completing the following Performance Assurance Tests.

### **Performance Assurance Test**

To verify the monitor works properly, perform the following test:

Step	Action
1	Using the supplied AC power cord, connect the monitor to the AC power source.
2	Verify that the AC LED is lit.
3	Do not connect any patient monitoring input connectors or cables to the monitor. If there are any such connections, disconnect them.
4	If the monitor is in Standby, press the On/Standby button. The monitor must perform the following sequence: a. The screen backlight illuminates. b. Three consecutively higher pitched “chimes” sound while the version numbers of the boot and operational software display. c. After successful completion, the main monitoring screen displays. No vital sign numeric values or waveforms display.
5	If an error codes display, or the screen remains blank, refer to Chapter 7, “Troubleshooting.”

### **Power-On Self-Test**

After you first press the On/Standby button, the monitor displays a startup screen and conducts a set of self-diagnostic test routines.

**Alarm Test****Tools Needed:**

- SpO<sub>2</sub> Extension Cable (10-64075-02)
- Clinical Dynamics Corp – SmartSat simulator (with Nellcor simulator cable)

Step	Action										
1	Return to original factory settings. (See <i>Restoring Factory Settings</i> , page 6-10.)										
2	Connect SpO <sub>2</sub> simulator cable to the SpO <sub>2</sub> adapter cable. Connect the cable to the SpO <sub>2</sub> patient monitoring input connector.										
3	Set the simulator as follows: <table> <tr> <th>Item</th><th>Setting</th></tr> <tr> <td>Oximeter</td><td>N. Oximax</td></tr> <tr> <td>SpO<sub>2</sub>%</td><td>81</td></tr> <tr> <td>BPM</td><td>36</td></tr> <tr> <td>Pulse Mod</td><td>0.50%</td></tr> </table>	Item	Setting	Oximeter	N. Oximax	SpO <sub>2</sub> %	81	BPM	36	Pulse Mod	0.50%
Item	Setting										
Oximeter	N. Oximax										
SpO <sub>2</sub> %	81										
BPM	36										
Pulse Mod	0.50%										
4	Press the On/Standby button to turn the monitor On.										
5	After the normal power-up sequence, verify that the SpO <sub>2</sub> % display initially indicates zero, or is blank.										
6	Verify that the following monitor reaction occurs: <ol style="list-style-type: none"> <li>After approximately 45 seconds, the monitor displays saturation and heart rate as specified by the tester. Verify that the values are within the following tolerances: <ul style="list-style-type: none"> <li>– Oxygen Saturation Range 79% to 83%</li> <li>– Heart Rate Range 33 to 39 BPM</li> </ul> </li> <li>The audible alarm sounds and both the SpO<sub>2</sub>% and Heart Rate (HR) displays flash, indicating both parameters have violated the default alarm limits.</li> <li>The HR tone is heard. For this test, the HR tone source must be set to SpO<sub>2</sub> from the Heart Rate Menu.</li> </ol>										
7	Press the Alarm Silence button to temporarily silence the audible alarm.										
8	Verify the following: <ol style="list-style-type: none"> <li>The audible alarm remains silenced.</li> <li>The crossed-out bell icon displays in each numeric frame on the screen.</li> <li>The SpO<sub>2</sub>% and HR displays continue flashing.</li> <li>The HR tone remains audible.</li> <li>The audible alarm returns within 120 seconds.</li> </ol>										



**Volume Control Test****Tools Needed:**

- SpO<sub>2</sub> Extension Cable (10-64075-02)
- Clinical Dynamics Corp – SmartSat simulator (with Nellcor simulator cable)

Step	Action										
1	Connect SpO <sub>2</sub> simulator cable to the SpO <sub>2</sub> adapter cable. Connect the cable to the SpO <sub>2</sub> patient monitoring input connector.										
2	Set the simulator as follows: <table border="1"> <thead> <tr> <th>Item</th><th>Setting</th></tr> </thead> <tbody> <tr> <td>Oximeter</td><td>N. Oximax</td></tr> <tr> <td>SpO<sub>2</sub>%</td><td>81</td></tr> <tr> <td>BPM</td><td>70</td></tr> <tr> <td>Pulse Mod</td><td>5.00%</td></tr> </tbody> </table>	Item	Setting	Oximeter	N. Oximax	SpO <sub>2</sub> %	81	BPM	70	Pulse Mod	5.00%
Item	Setting										
Oximeter	N. Oximax										
SpO <sub>2</sub> %	81										
BPM	70										
Pulse Mod	5.00%										
3	Power the monitor On. Verify that the values are within the following tolerances: <ul style="list-style-type: none"> <li>– Oxygen Saturation Range 79% to 83%</li> <li>– Heart Rate Range 67 to 73 BPM</li> </ul>										
4	Press the Alarm Silence button to temporarily silence the audible alarm.										
5	Verify that the heart rate tone source, found in the Heart Rate Menu, is set to SpO <sub>2</sub> .										
6	Press the Volume button on the monitor's front panel. Within 3 seconds of having pressed the button, rotate the navigation wheel clockwise to verify that the beeping heart rate tone sound level increases.										
7	Wait 3 seconds. Press the Volume button and rotate the wheel counter-clockwise and verify that the beeping heart rate tone decreases until it is no longer audible. Rotate the wheel clockwise to return the beep volume to a comfortable level.  After 3 seconds with no wheel activity, the volume adjust function terminates.										

**6.12 Preventive Maintenance Tests**

Preventive maintenance refers specifically to the service tests required to make sure the monitor measurement results are accurate. In cases where the performance of NIBP is in question or could have been configured during repair, the complete set of NIBP tests described in this service manual should be used. (See page 6-7.)

The tests in this section verify the functionality of the monitor's pneumatic system. All of these tests, with the exception of the Basic Pneumatic Leakage (BPL) Test, require the use of an NIBP simulator.

**NOTE**

The monitor must be placed in Diagnostic Mode, with the NIBP test screen active for each of the NIBP tests. To place the monitor into this mode, see page 6-4.

**Tools Needed for NIBP Testing:**

- NIBP cuff (AN4K-AC017)
- NIBP tubing (AN4K-AC019)
- Bio-Tek BP Pump 2 simulator or equivalent, with an internal test volume of 310 ml and CONDEC Model DLR334 Pressure Indicator.

***Pneumatic System Functionality***

The following tests must be performed to verify pneumatic system functionality. Perform these tests in the following order:

1. Pressure Transducer Accuracy
2. Pneumatic Leakage
3. Inflation Rate
4. Over-Pressure
5. Deflation Rate

***Pressure Transducer Accuracy Test***

This test verifies the pressure accuracy of the monitor's pressure transducer.

<b>Step</b>	<b>Action</b>
1	Place the monitor in <b>Diagnostic Mode</b> with the NIBP test screen active.
2	Confirm that the simulator displays "Leak Test" (see steps 1 and 2, in the previous table).
3	Press the <b>Volume</b> button to ensure that both valves are closed.
4	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by doing the following: a. Press the <b>Contrast</b> button on the monitor's front panel. b. If needed, zero the simulator (see "To Zero the Simulator" on Page 6-10).
5	Press <b>Start</b> on the simulator.
6	Allow 15-20 seconds for the pressure to stabilize. The pressure displayed on the monitor and on the simulator should be within 5 mmHg (0.7 kPa) of one another. Document the difference between the simulator value and the monitor value.
7	Press the <b>Stop</b> button on the simulator to stop the test.
8	Press and hold the <b>Volume</b> button until the monitor displays a pressure of 0 mmHg or kPa.
9	If no further NIBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

**Pneumatic Leakage Test**

This test verifies the integrity of the pneumatic system.

Step	Action
1	Turn the simulator On.
2	Perform the following sequence: a. Press the <b>Home</b> button. b. Press the <b>Pressure Tests</b> button. c. Press the <b>Pressure Leak Test</b> button. d. Press the <b>Setup</b> button. e. Press <b>3, 0, 0</b> , then <b>Enter</b> . f. Set the <b>Cuff</b> to <b>Internal</b> .
3	Confirm that the simulator test screen is active and displays “Leak Test.”
4	Press the <b>Volume</b> button to ensure that both valves are closed.
5	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by pressing the <b>Contrast</b> button on the monitor’s front panel.
6	Press the <b>NIBP</b> button on the monitor’s front panel to activate the pump. Hold the button until the monitor displays a pressure of approximately 250 mmHg (33.3 kPa).
7	Allow 15-20 seconds for the pressure to stabilize. Record the pressure displayed on the monitor.
8	Start a one minute time. After one minute, record the pressure displayed again. The pressure should drop by no more than 6 mmHg (0.8 kPa) during the one minute.
9	Press and hold the <b>Volume</b> button until the monitor displays a pressure of 0 mmHg or kPa.
10	If no further NIBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

**Inflation Rate Test**

This test verifies the inflation rate of the monitor.

Step	Action
1	Turn the simulator On.
2	Perform the following sequence: a. Press the <b>Home</b> button. b. Press the <b>Pressure Tests</b> button. c. Press the <b>Pressure Leak Test</b> button. d. Press the <b>Setup</b> button. e. Press <b>3, 0, 0</b> , then <b>Enter</b> . f. Set the <b>Cuff</b> to <b>Internal</b> .
3	Press the <b>Volume</b> button to ensure that both valves are closed.
4	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by doing the following: a. Press the <b>Contrast</b> button on the monitor’s front panel. b. If needed, zero the simulator (see “To Zero the Simulator” on Page 6-10).
5	Press the <b>NIBP</b> button on the monitor’s front panel to activate the pump, and simultaneously start the timer. Hold the button until the monitor displays a pressure of 250 mmHg (33.3 kPa), then stop the timer. The inflation rate should be between 1 and 6 seconds.
6	Press and hold the <b>Volume</b> button until the monitor displays a pressure of 0 mmHg or kPa.
7	If no further NIBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

**NOTE**

The pneumatic system includes an over-pressure safety limit function and a safety period time-out function. These safety functions may interfere with NIBP tests described in this section. In order to avoid activating these safety functions, do not pressurize the system above 270 mmHg (36 kPa) and do not pressurize the system for time periods that exceed 150 seconds.

**NOTE**

The over-pressure relief may activate and automatically deflate the cuff. For more information on the NIBP safety functions, see page 6-10.

**Over-Pressure Test**

This test verifies the functionality of the over-pressure relief system of the monitor.

Step	Action
1	Turn the simulator On.
2	Perform the following sequence: a. Press the <b>Home</b> button. b. Press the <b>Pressure Tests</b> button. c. Press the <b>Pressure Relief</b> button. d. Press the <b>Setup</b> button. e. Press <b>3, 3, 5</b> , then <b>Enter</b> .
3	Confirm that the simulator is active and displays "Relief Valve Test."
4	Press the Volume button to ensure that both valves are closed.
5.	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by doing the following: a. Press the <b>Contrast</b> button on the monitor's front panel. b. If needed, zero the simulator (see "To Zero the Simulator" on page 6-10).
6	Press the <b>Start</b> button on the simulator. The peak value (X4) shown on the simulator should be between 270 mmHg and 330 mmHg (35.9 kPa and 43.9 kPa). The pressure should return to 0 automatically on the monitor and simulator. Both conditions should be true for the monitor to pass this test.
7	If no further NIBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

**Deflation Rate Test**

This test verifies the deflation rate of the monitor.

Step	Action
1	Turn the simulator On.
2	Perform the following sequence: a. Press the <b>Home</b> button. b. Press the <b>Pressure Tests</b> button. c. Press the <b>Pressure Leak Test</b> button. d. Set the <b>Cuff</b> to <b>Internal</b> .
3	Confirm that the simulator is active and displays "Leak Test."
4	Press the Volume button to ensure that both valves are closed.
5	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by doing the following: a. Press the Contrast button on the monitor's front panel. b. If needed, zero the simulator (see "To Zero the Simulator" on page 6-10).
6	Note — Complete steps 6 – 9 within 150 seconds. Press and hold the <b>NIBP</b> button on the monitor's front panel and inflate to $250 \pm 10$ . Don't go over 270, or safety deflation may occur. (Slow the inflation rate by pulsing the button when the pressure is over 200).
7	Allow 15-20 seconds for the pressure to stabilize.
8	Press and hold the "Alarm off" button on the monitor to release the pressure in steps of 3 mmHg (.4 kPa). Simultaneously, start the timer.
9	Stop the timer when the pressure drops below 150 mmHg (20 kPa). Calculate the deflation rate (X5): (starting pressure - 150)/# of seconds. The deflation rate should be 3.3 mmHg/s $\pm 1.5$ mmHg/s (0.44 kPa/s $\pm 0.2$ kPa/s).
10	Press and hold the Volume button until the monitor displays a pressure of 0 mmHg or kPa.
11	If no further NIBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

**Basic Pneumatic Leakage (BPL) Test**

The purpose of this test is to verify the integrity of the NIBP pneumatic system after the monitor has been opened. This includes all external and internal tubing connections.

No simulator is required for this test, and results do not need to be reported.

Step	Action
1	Attach the NIBP cuff to the NIBP tubing and the tubing to the NIBP patient monitoring input connector.
2	Wrap the cuff around itself and place it on a table for the test. <b>DO NOT place the cuff on your arm.</b>
3	Turn the monitor On and enter the NIBP test screen located within <b>Diagnostic Mode</b> .
4	Press the <b>Volume</b> button to close valves.
5	a. Press and hold the <b>NIBP Start/Stop</b> switch until the monitor's screen reads "250 mmHg" or "33.3 kPa". b. Wait 15-20 seconds to allow the pressure to stabilize.
6	a. Note the value on the screen (P1), then start a timer. b. After one minute, note the value on the screen (P2). c. Calculate the difference between the two values (P1 - P2). The value should be less than or equal to 6 mmHg (0.8 kPa).
7	Press and hold the <b>Volume</b> button until the screen shows the pressure has released and the value is 0 mmHg or kPa.
8	Turn the monitor Off.

---

**NOTE**

If the test fails, ensure the integrity of the cuff and tubing, then test again. If the test fails again, verify the integrity of all the pneumatic tubing inside the monitor.

**6.13 Performance Procedures**

The following accuracy and performance procedures are designed to be completed to verify the accuracy and performance of the monitor. They must be performed, according to the frequency specified in the section titled, "Recommendations for Testing Frequency" on page 6-3.

**Battery Performance Test**

The battery performance test should be performed every two years, before monitor repairs, or whenever the battery is suspected as being a source of the problem. Before performing the battery performance test, verify that the battery is fully charged (see "Charging the Battery" on page 4-5).

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**NOTE**

Before beginning this test, ensure that the monitor is disconnected from the AC power source, and that the battery is fully charged.

---

**Tools Needed:**

- NIBP tubing (AN4K-AC019)
- Bio-Tek BP Pump 2 simulator or equivalent, with an internal test volume of 310 ml

Step	Action
1	Connect the NIBP simulator to the monitor via the NIBP tubing.
2	Set the NIBP simulator to a pressure setting of 120/80 mmHg (16/11 kPa), and a heart rate of 80 BPM.
3	With the monitor Off, press the <b>On/Standby</b> button. (When the monitor is turned on, the battery icon may initially indicate a higher charge than it actually holds - wait 5 minutes or until after an NIBP measurement for an accurate battery reading.)
4	Use the navigation wheel to select the <b>NIBP Menu</b> and set the <b>Automatic Interval Mode</b> option to 15 minutes. Select <b>Return</b> to exit the menu.
5	Press the <b>NIBP</b> button on the monitor's front panel to start the first NIBP measurement. Subsequent NIBP measurements are taken automatically every 15 minutes.
6	Verify that the battery icon displays at the bottom of the display. Note the time. (At least one segment of the battery icon should be filled.)
7	Keep the monitor on for three hours or until the low battery technical alarm occurs. If the technical alarm has not occurred, the monitor has passed and the battery must be recharged.
8	If the technical alarm occurs, record the time and continue testing. As the battery ages, this time will become shorter. If the loss of monitoring alarm has not occurred, the monitor has passed and the battery must be recharged.
9	If the loss of monitoring alarm has occurred or if the monitor has automatically shut down prior to three hours, it is recommended that the battery be replaced. (See <i>Removing the Battery</i> on page 8-2..) <b>Press any front panel button on the monitor to terminate this alarm.</b>

**Temperature Test**

The accuracy of the monitor's temperature measurements is  $\pm 0.1^{\circ}\text{C}$  ( $\pm 0.2^{\circ}\text{F}$ ). In the procedure below, add the tolerance of the simulator to the acceptable range of readings.

**Tools Needed:**

- Fogg System, TP400 Temperature Probe Simulator or equivalent
- Fogg System, 7242-0001 Cable (1/4" to 1/4", 3-conductor)

**NOTE**

The instructions below apply to the Dynatech Nevada MedSim 300.

Step	Action
1	Verify the monitor is in Standby. Connect the temperature cable to the appropriate connector on the temperature simulator.
2	Connect the temperature cable to the Temperature patient monitoring input connector.
3	Set the temperature simulator as follows: a. Temperature $37^{\circ}\text{C}$ ( $98.6^{\circ}\text{F}$ ) b. Probe Type: YSI 400 Series
4	Press the <b>On/Standby</b> button to turn the monitor On.
5	After the power-up sequence, verify the temperature reads $37^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$ ( $98.6^{\circ}\text{F} \pm 0.2^{\circ}\text{F}$ if Fahrenheit is selected as the temperature unit).
6	Turn the monitor to Standby.

**ECG/Respiration Performance**

This section includes tests for both ECG and Respiration.

**Tools Needed for both ECG and Respiration Testing:**

- ECG lead sets – 10-64669-01 (AAMI) or 10-64669-03 (IEC)
- ECG patient cables – 10-64667-01 (ICU)

**ECG Test**

The accuracy of the monitor's ECG measurements is  $\pm 5$  BPM. In the following procedure, add the tolerance of the simulator to the acceptable range of readings.

Step	Action
1	Verify that the monitor is in Standby. Connect the ECG leads to the appropriate jacks on the ECG simulator.
2	Connect the leads to the ECG trunk cable. Connect the cable to the ECG patient monitoring input connector.
3	Set the ECG simulator as follows: <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <b>Set</b> Heart Rate (HR) Lead select </div> <div style="text-align: center;"> <b>To</b> 30 BPM II </div> </div>
4	Press the On/Standby button to turn the monitor On.
5	After the power-up sequence, verify the following monitor reactions: a. After at least five heartbeats, the monitor displays a heart rate of $30 \pm 5$ BPM. b. The audible alarm sounds and the Heart Rate frame flashes, indicating heart rate is below the default lower alarm limit.
6	Press the Alarm Silence button twice (on the monitor's front panel) to invoke the Silence/Reset mode.
7	Increase the heart rate setting on the ECG simulator to 250 BPM. After at least five heartbeats, verify that the monitor displays a heart rate of $240 \pm 5$ BPM.
8	Verify that the audible alarm sounds and the Heart Rate frame flashes, indicating that the heart rate is above the default upper alarm limit.
9	Press the Alarm Silence button twice (on the monitor's front panel) to invoke the Silence/Reset mode.
10	Decrease the heart rate setting on the ECG simulator to 120 BPM. After at least five heartbeats, verify that the monitor displays a heart rate of $120 \pm 5$ BPM.
11	Disconnect the LL lead from the ECG simulator. Verify that the Leads Off alarm message displays. -?- displays in the Heart Rate frame, and the low priority "Leads Off" INOP sounds.
12	Reconnect the LL lead to the ECG simulator. Verify that the Leads Off alarm message no longer displays and the audible alarm is silenced.
13	Repeat steps 11 and 12 for LA and RA leads, then turn your monitor Off.



### Respiration Test

The accuracy of the monitor's respiration measurements is  $\pm 3$  breaths per minute. In the procedure below, add the tolerance of the simulator to the acceptable range of readings.

Step	Action
1	Verify that the monitor is in Standby. Connect the ECG leads to the appropriate jacks on the ECG simulator.
2	Connect the ECG leads to the ECG trunk cable.
3	Connect the cable to the ECG patient monitoring input connector.
4	Set the simulator for a respiration rate of 120 breaths per minute.
5	Press the <b>On/Standby</b> button to turn the monitor On.
6	After the power-up sequence, verify the following monitor reactions: a. The monitor displays a respiration rate of $120 \pm 3$ breaths per minute. b. The audible alarm sounds and the Respiration Rate frame flashes, indicating the respiration rate is above the default upper alarm limit.
7	Press the <b>Alarm Silence</b> button to silence the alarm.
8	Decrease the respiration rate setting on the respiration simulator to 20 breaths per minute. Verify that the monitor displays a respiration rate of $20 \pm 3$ breaths per minute.

### SpO<sub>2</sub> Performance

SpO<sub>2</sub> testing includes the following tests:

- Dynamic Operating Range
- LED Excitation Test

#### Tools Needed for SpO<sub>2</sub> Tests:

- Clinical Dynamics Corp – SmartSat simulator (with Nellcor simulator cable)
- SpO<sub>2</sub> Extension Cable (10-64075-02)
- SpO<sub>2</sub> reusable sensor, adult finger (AN4K-AC001)

### LED Excitation Test

This procedure uses normal system components to test circuit operation. A SpO<sub>2</sub>, adult finger, reusable sensor is used to examine LED intensity control. The red LED is used to verify intensity modulation caused by the LED intensity control circuit.

Step	Action
1	Connect an SpO <sub>2</sub> sensor to the monitor.
2	Press the On/Standby button to turn the monitor On.
3	After the monitor completes its normal power-up sequence, verify that the sensor LED is brightly lit.
4	Slowly move the sensor LED in proximity to the photo detector element of the sensor. Verify, as the LED approaches the optical sensor, that the LED intensity decreases.
5	Open the sensor and take note that the LED intensity increases.
6	Repeat Step 5 and the intensity again decreases. This variation is an indication that the microprocessor is in proper control of LED intensity.
7	Turn the monitor to Standby.

**Dynamic Operating Range Test**

The following test sequence verifies proper monitor operation over a range of input signals.

Step	Action
1	Press the On/Standby button to turn the monitor on.
2	Connect SpO <sub>2</sub> simulator cable to the SpO <sub>2</sub> adapter cable. Connect the cable to the SpO <sub>2</sub> patient monitoring input connector.
3	Set the simulator as indicated in the table below. Verify that the monitor readings are within the indicated tolerances. Allow the monitor several seconds to stabilize the readings.
4	Turn the monitor to Standby.

**Table 6-1. Settings and Monitor Indications**

Simulator Settings					Monitor Indications	
SpO <sub>2</sub> %	Pulse Rate	Ambient Light Freq	Ambient Light AC Level	Modulation	SpO <sub>2</sub>	Pulse Rate
81	36	120	200	0.50%	79-83*	33-39*
81	112	120	200	5.00%	79-83*	109-115
81	201 <sup>a</sup>	120	10	0.50%	79-83*	195-207*
81	201 <sup>a</sup>	120	200	5.00%	79-83*	195-207*

An \* indicates values that produce an alarm. Press the Alarm Silence button to temporarily silence the audible alarm.

- a. For the pulse rate setting of 201 BPM, the pulse rate tolerance of 195 to 207 BPM is greater than  $\pm 3$  BPM accuracy specification on the monitor, due to the performance characteristics of the simulator.

**CO<sub>2</sub> Performance**

This test checks the performance of your CO<sub>2</sub> measurement for the monitor. This test uses calibration equipment that can be ordered, (See page 6-5). Refer to the documentation accompanying the equipment for detailed instructions. The procedure is summarized in the following steps:

- Barometric Pressure Check and Calibration, if required
- Leakage Check
- Pump Check
- Flow Check and Calibration, if required
- CO<sub>2</sub> Cal Check and Calibration, if required

**NOTE**

Allow 5 seconds between individual service procedures in order to ensure stable equipment conditions.

Tools Needed for CO<sub>2</sub> Tests:

- Electronic Flowmeter
- Tubing
- CO<sub>2</sub> Patient Connector
- Cal 1 gas (5% CO<sub>2</sub>)

Also needed is a local barometric pressure rating received from a reliable source, such as an airport, regional weather station, or hospital weather station. The pressure rating must be located at the same altitude as the hospital.

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**NOTE**

All steps must be performed in the same session.

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**Barometric Pressure Check and Calibration**

Check the barometric pressure value in the CO<sub>2</sub> module as follows:

Step	Action
1	Enter the <b>Power-Up Defaults Menu</b> (see <i>Power-Up Defaults Menu</i> on page 6-2 for instructions on accessing this menu).
2	Select the <b>Enter Diagnostic Mode?</b> option.
3	From the popup menu, select <b>Yes</b> . The <b>Diagnostic Menu</b> displays.
4	Select the <b>CO<sub>2</sub> Test</b> option.
5	Connect a FilterLine to the CO <sub>2</sub> patient monitoring input connector. This activates the pump in the CO <sub>2</sub> module.
6	Check the status line at the top of the screen. It will display “CO <sub>2</sub> pressure in mmHg (ambient/cell) xxx/yyy” where xxx is the ambient pressure and yyy is the measured cell pressure. The values are displayed with a resolution of 2 mmHg (0.3 kPa) up to 475 mmHg (63.2 kPa) and a resolution of 1 mmHg (0.1 kPa) from 475 mmHg (63.2 kPa) to 825 mmHg (109.7 kPa). Check whether the ambient pressure matches (within the acceptable tolerance of $\pm 12$ mmHg) the reference value you have received. If so, proceed to the <i>Leakage Check</i> . If the value is not correct, calibrate as follows.
7	Select <b>Set Barometric Pressure (mmHg)</b> . An adjustable value in mmHg is activated.
8	Select the value that matches the reference value received from a reliable local source, such as an airport, regional weather station or hospital weather station.
9	If the selected value is not within $\pm 12$ mmHg (1.6 kPa) of the current measured ambient pressure, verify the reference value by getting another reading from a different source. If the ambient pressure displayed also differs from the new reference by more than $\pm 12$ mmHg (1.6 kPa), the CO <sub>2</sub> module should be replaced.
10	Confirm the barometric pressure setting by clicking on the adjusted value so that it is no longer highlighted.
11	Check that the ambient pressure displayed in the CO <sub>2</sub> Pressure line at the top of the screen is the same as the value that you selected from the list in Step 8.

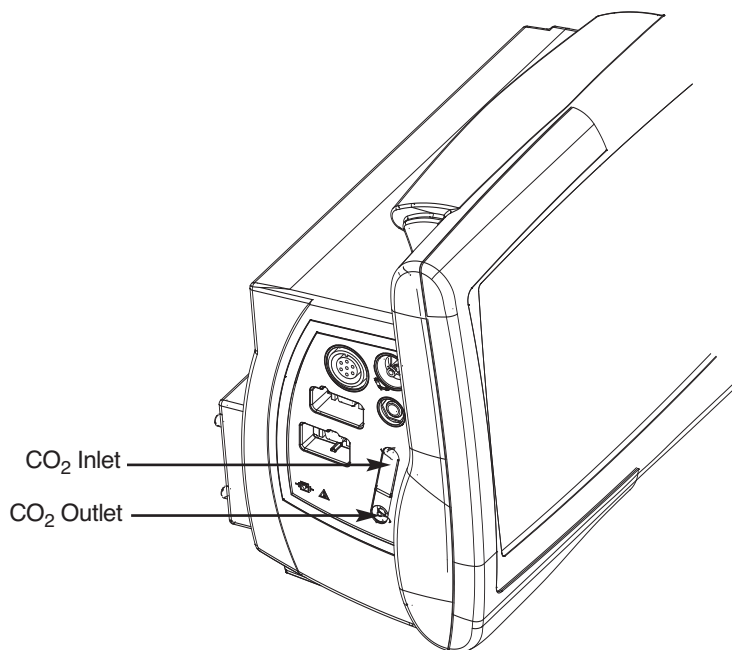
**Leakage Check**

The Leakage Check consists of two parts:

- Part 1 – Checking the tubing between the pump outlet and the CO<sub>2</sub> module outlet.
- Part 2 – Checking the tubing between the pump inlet and the FilterLine inlet.

**NOTE**

Check the flowmeter's user's guide for details on how to make a correct flow reading.



**Figure 6-2. CO<sub>2</sub> Inlet and Outlet.**

**Part 1**

Step	Action
1	Check the ambient and cell pressure shown in the status line on the screen. The cell pressure should be approximately 20 mmHg (2.7 kPa) lower than the ambient pressure.
2	Connect the flowmeter outlet to the FilterLine inlet using a flexible connecting tube.
3	Block the CO <sub>2</sub> module outlet using your fingertip and observe the flowmeter display. The value on the flowmeter should decrease to between 0 and 4 ml/minute. If the value is not within the tolerance limits, there is a leak between the pump outlet and the CO <sub>2</sub> module gas outlet.
4	If a leak is found in Step 3, open the CO <sub>2</sub> module and check the tubing connections at the pump outlet and the module CO <sub>2</sub> gas outlet. If the connections are good, then there is leakage in the module and the CO <sub>2</sub> module must be exchanged.

*Part 2*

Step	Action
1	Disconnect the flowmeter from the Part 1 setup and connect the flowmeter inlet to the CO <sub>2</sub> module gas outlet. (Refer to figure 6-3.)
2	Leave the FilterLine connected to the CO <sub>2</sub> module inlet. Leave other end of line open.
3	Block the inlet of the FilterLine using your fingertip and observe the flowmeter display. The value on the flowmeter should decrease to between 0 and 4 ml/minute. If the value is within the tolerance limits, there are no leaks and the leak check is completed. Proceed to the <i>Pump Check</i> .
4	If the value is not within the tolerance limits, there is a leak between the FilterLine inlet and the pump inlet.
5	Check the FilterLine connections and open the monitor to check the tubing connections at the pump inlet and the CO <sub>2</sub> module gas inlet. If the connections are good, try replacing the FilterLine and repeating the leakage check. If the situation remains, there is a leak in the tubing and the CO <sub>2</sub> module must be exchanged.

*Pump Check*

Step	Action
1	Connect the flowmeter inlet to the CO <sub>2</sub> gas outlet.
2	Connect the FilterLine to the CO <sub>2</sub> module inlet. Leave other end of line open.
3	Block the inlet of the FilterLine using your fingertip and observe the cell pressure to the right of the slash symbol on the top row of the CO <sub>2</sub> Test display screen.  The cell pressure should be more than 120 mmHg below the ambient pressure shown. If the pressure difference is less than 120 mmHg, the pump is not strong enough and should be replaced (regardless of the Pump Op Time).

*Flow Rate Check and Calibration*

Step	Action
1	Connect the flowmeter to the CO <sub>2</sub> FilterLine.
2	On the flowmeter, check the flow that the CO <sub>2</sub> pump draws. The nominal value is 50; the acceptable limits are 42.5 and 57.5 ml/minute. If the value is within these limits, proceed to the CO <sub>2</sub> gas calibration check. If not within the limits, calibrate as follows.
3	Select <b>Flow Rate Check and Calibration</b> . Adjust the flow in the monitor by selecting <b>Increase Flow</b> or <b>Decrease Flow</b> until it is as close as possible to 50 ml/minute as indicated on the flowmeter gauge. The pump voltage displayed on the second row of the CO <sub>2</sub> Test screen will vary as the flow is changed.
4	When the flow is set as close as possible to 50 ml/minute, select <b>Store Flow</b> to confirm the setting.

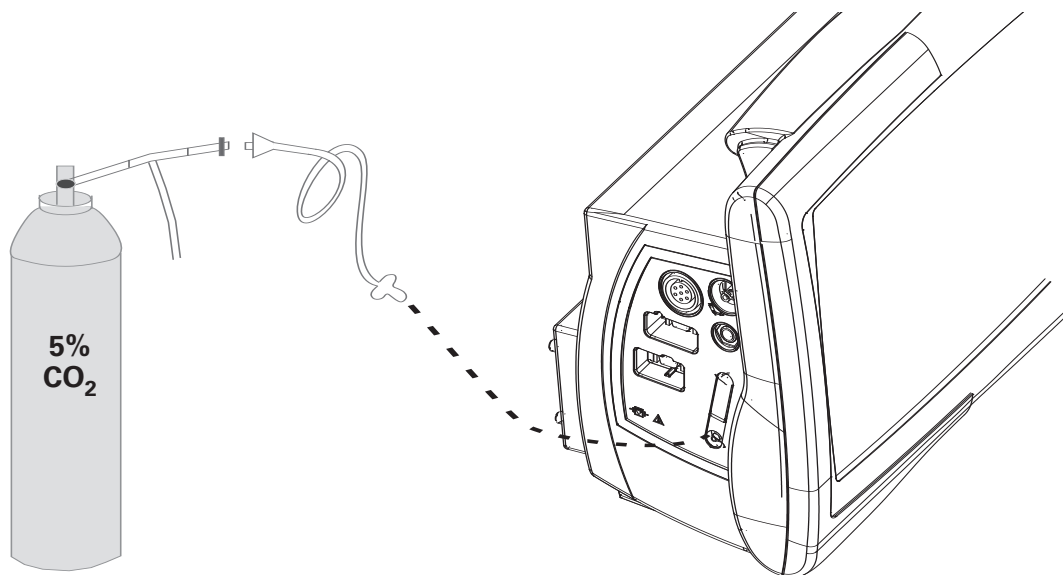
**NOTE**

If the adjusted flow is not stored within 60 seconds of the adjustment, the old flow setting is restored. If the flow cannot be adjusted to within tolerance, the pump should be replaced. If the flow adjustment still cannot be made, this indicates a fault in the CO<sub>2</sub> module, which must be replaced.

**CO<sub>2</sub> Gas Measurement Calibration Check**

With the monitor on, wait at least 20 minutes before checking the calibration. The filter line must be attached.

Step	Action
1	Check that the 5% calibration gas is connected. (See Figure 6-3.)
2	Calculate the expected measurement value in mmHg as follows: $0.05 \times (\text{ambient pressure}) / 1.03 = \text{value mmHg}$ i.e., $0.05 \times 736 \text{ mmHg} / 1.03 = 35.7 \text{ mmHg}$ (with an ambient pressure of 736 mmHg) <i>Note: Dividing by 1.03 compensates for the dry calibration gas at room temperature, relative to breath gases containing water vapor and at body temperature.</i>
3	Highlight and depress <b>CO<sub>2</sub> Calibration</b> . Wait for the status message “CO <sub>2</sub> module reset in progress” to disappear. Depress the button on the canister to allow 5% CO <sub>2</sub> gas to flow into the monitor. Allow the displayed CO <sub>2</sub> value (third row of CO <sub>2</sub> Test menu) to stabilize.
4	Check that the CO <sub>2</sub> value on the monitor matches the calculated mmHg value $\pm 2.6$ mmHg. If the value is outside the tolerance, calibrate as described in Steps 5 through 9.
5	If not already connected, connect the 5% calibration gas.
6	Highlight and depress <b>CO<sub>2</sub> Calibration</b> to enter the Calibration sub-menu. Wait for the status message “CO <sub>2</sub> module reset in progress” to disappear.
7	Select the value for the calibration gas (the default value is 5%).
8	Select <b>Start Calibration</b> and press and hold the valve on the calibration gas to allow CO <sub>2</sub> gas to flow into the monitor. Allow the value to stabilize before the start of the calibration. Hold the valve open until the monitor gives a prompt that the gas can be removed.
9	The CO <sub>2</sub> module calibrates and prompts when calibration is successful.



**Figure 6-3. Connecting the Calibration Gas to the LIFEGARD II.**

**Calibration Verification**

Step	Action
1	Depress button on the 5% gas valve and allow the value to stabilize
2	Check that the value displayed on the monitor is correct and within the tolerance (see Step 2 in previous section).

**Serial Interface and Nurse Call Signal Test**

Perform the following procedure to test the serial port voltages. The test is qualitative and only verifies that the serial interface port is powered correctly, and that the Nurse Call signal (Pin 9) is operational. The serial connector is a male DB-9 located on the monitor's rear panel, identified by the RS-232 symbol.

Tools Needed:

- Clinical Dynamics Corp – SmartSat simulator (with Nellcor simulator cable)
- SpO<sub>2</sub> extension cable (10-64075-02)

Step	Action										
1	Verify that the Nurse-Call Signal is "On" in the setup menu.										
2	Turn the monitor On.										
3	Set up the DMM with the function set to VDC at a range of 10 volts.										
4	Connect the DMM negative lead to connector pin 5 (GND), or the shell of the RS-232 connector.										
5	Referring to <i>Table 6-2. Serial Interface Voltages</i> , connect the DM positive lead to each pin in turn, and verify the voltage values listed. Voltage for pin 9 is that listed from the No Alarm condition.										
6	Connect SpO <sub>2</sub> simulator cable to the SpO <sub>2</sub> adapter cable. Connect the cable to the SpO <sub>2</sub> patient monitoring input connector.										
7	Set the simulator switches as follows: <table data-bbox="597 1312 836 1501"> <tr> <th>Item</th><th>Setting</th></tr> <tr> <td>Oximeter</td><td>Nellcor</td></tr> <tr> <td>SpO<sub>2</sub>%</td><td>81</td></tr> <tr> <td>BPM</td><td>36</td></tr> <tr> <td>Pulse Mod</td><td>0.50%</td></tr> </table>	Item	Setting	Oximeter	Nellcor	SpO <sub>2</sub> %	81	BPM	36	Pulse Mod	0.50%
Item	Setting										
Oximeter	Nellcor										
SpO <sub>2</sub> %	81										
BPM	36										
Pulse Mod	0.50%										
8	Verify that the monitor is responding to the SpO <sub>2</sub> simulator signal and the audible alarm is sounding. If desired, press the <b>Alarm Silence</b> button to temporarily silence the audible alarm.										
9	Connect the DMM positive lead to pin 9 and verify the voltage value listed in <i>Table 6-2. Serial Interface Voltages</i> . The voltage for pin 9 is that listed for the Alarm Underway condition.										

Table 6-2. Serial Interface Voltages

Pin	Signal	Direction	Measurement (V)		
			Min	Typical	Max
1	not used		-0.4	0.0	0.4
2	RXD	input	-0.4	0.0	0.4
3	TXD	output	±0.5	±7.1	±7.25
4	DTR	output	-5.0	-7.0	-15.0
5	GND		-0.4	0.0	0.4
6	DSR	input	-0.4	0.0	4.0
7	RTS	output	-5.0	-7.1	-7.25
8	CTS	input	-0.4	0.0	0.4
9	Alarm Out (no alarm)	output	-5.0	-7.1	-7.25
9	Alarm Out (alarm underway)	output	5.0	7.1	7.25

## 6.14 Patient Safety Tests

The safety tests meet the standards of, and are performed in accordance with IEC 60601-1, Clause 19 (EN60601-1, Second Edition, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03).

The LIFEGARD II patient monitor is a Class I device. It requires a protective earth (ground) wire. Keep this in mind when performing the following test procedures.

There are two categories of safety tests:

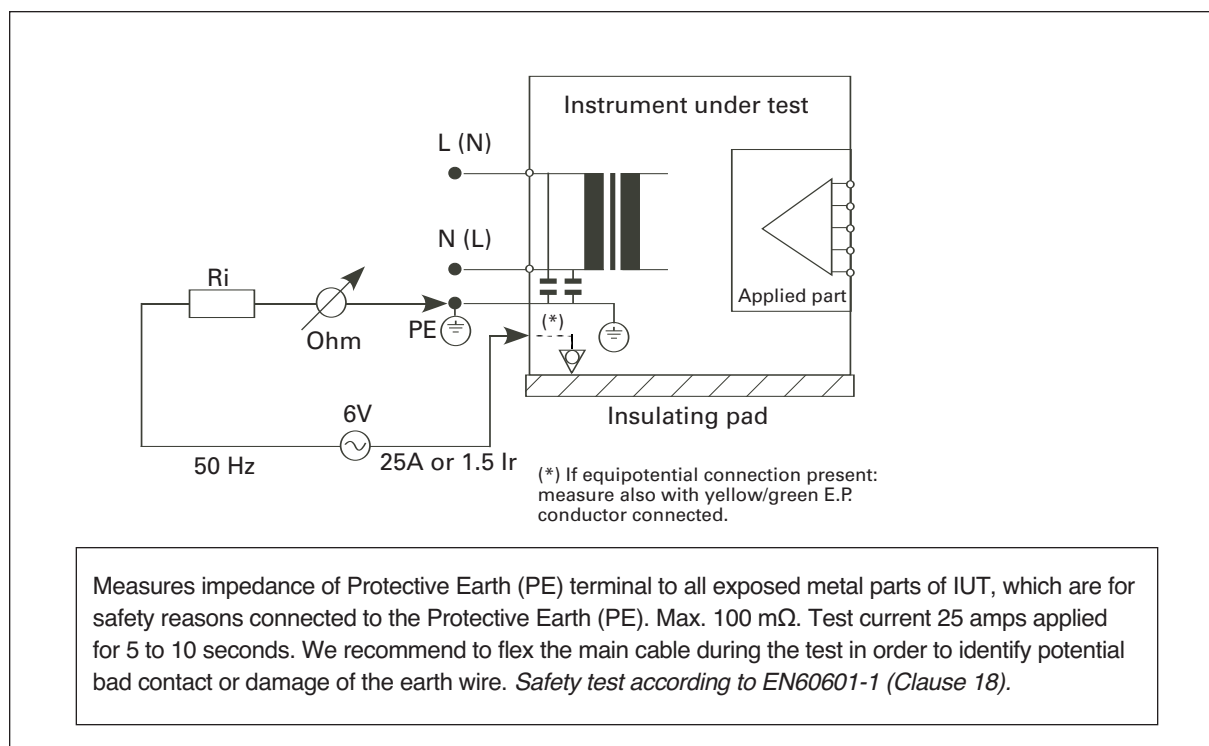
- Ground Integrity
- Electrical Leakage

### Ground Integrity

Table 6-3. Ground Integrity

Test or “Inspection” to Perform	Expected Test Results
Protective Earth	With mains cable:
See <i>Safety Test Diagram - Protective Earth</i> on page 6-26.	Maximum impedance no greater than 100 mΩ





**Figure 6-4. Safety Test Diagram – Protective Earth**

### ***Electrical Leakage***

The following tests verify the electrical leakage of the monitor:

- Earth Leakage Current
- Enclosure Leakage Current
- Patient Leakage Current
- Patient Source Current, with Mains Voltage on the Applied Part

### **WARNING**



Perform all leakage tests any time the unit is opened.

### ***Earth Leakage Current***

This test is in compliance with IEC 60601-1 (Earth Leakage Current). In locations where mains voltage is 100-120 volts, the applied voltage is 132 volts. In locations where mains voltage is 220-240 volts, the applied voltage is 264 volts. The applied AC frequency should be the same as the local mains (50 or 60 Hz).

All measurements shall be made with the power switch in both On and Off positions.

1. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.
2. Perform test as recommended by analyzer operating instructions.

Earth leakage current is measured under various conditions of the AC mains and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated in Table 6-4.

**Table 6-4. Earth Leakage Current Values**

Test Condition	Polarity	Allowable Leakage Current
Normal	Normal	300 $\mu$ A
	Reversed	300 $\mu$ A
S.F.C. <sup>a</sup>	Normal	1000 $\mu$ A
Open Supply	Reversed	1000 $\mu$ A

a. S.F.C. = Single Fault Condition

#### ***Enclosure Leakage Current***

This test is compliant with EN60601-1 (Enclosure Leakage Current). Test at 110% of the nominal line voltage.

Step	Action
1	Connect the AC mains power cord to the analyzer as recommended by the analyzer operating instructions.
2	Using the appropriate test cable, connect the analyzer to either of the screws on the back of the monitor, next to the handle.
3	Turn the monitor on.
4	Perform the test as recommended by the analyzer operating instructions.

The analyzer leakage current indication must not exceed the values listed below.

**Table 6-5. Enclosure Leakage Current** (EN60601-1 (1990 + A1, A2, A11, A12, A13) and UL2601 (2nd Ed. 1997) US Deviations)

Test Condition	Polarity	Allowable Leakage Current
Normal	Normal	100 $\mu$ A
	Reversed	100 $\mu$ A
S.F.C. Open	Normal	300 $\mu$ A
Protective Earth	Reversed	300 $\mu$ A

#### ***Patient Leakage Current***

This test measures patient leakage current in accordance with EN60601-1, Clause 19, for Class I, type CF equipment. Patient leakage current in this test is measured from any individual patient connection to earth (power ground).

This test requires a sample patient cable for each device parameter. These must be configured as recommended by the safety analyzer operating instructions.

Step	Action
1	Configure the electrical safety analyzer as recommended by the analyzer operating instructions.
2	Connect the monitor's AC mains power cord to the analyzer as recommended by analyzer operating instructions.
3	Connect the ECG test cable between the ECG connector on the monitor and the appropriate input connector on the analyzer.
4	Turn the monitor On.
5	Perform the test as recommended by the analyzer operating instructions.  Patient leakage current is measured under various conditions of the AC mains and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated below.
6	Repeat the test for SpO <sub>2</sub> and temperature patient connections, using appropriate test cables.

Table 6-6. Patient Leakage Current Values

Test Condition	Polarity	Allowable Leakage Current (Max.) — Type CF
Normal	Normal	10 $\mu$ A
	Reversed	10 $\mu$ A
S.F.C. Open Earth Ground	Normal	50 $\mu$ A
	Reversed	50 $\mu$ A

***Patient Leakage Current, with Mains Voltage on the Applied Part***

This test measures patient leakage current in accordance with EN60601-1, Clause 19, for Class I, type CF equipment. In this test, 110% of mains voltage is applied between each patient connection and earth (power ground). Patient leakage current is then measured from any individual patient connection to earth.

**WARNING**

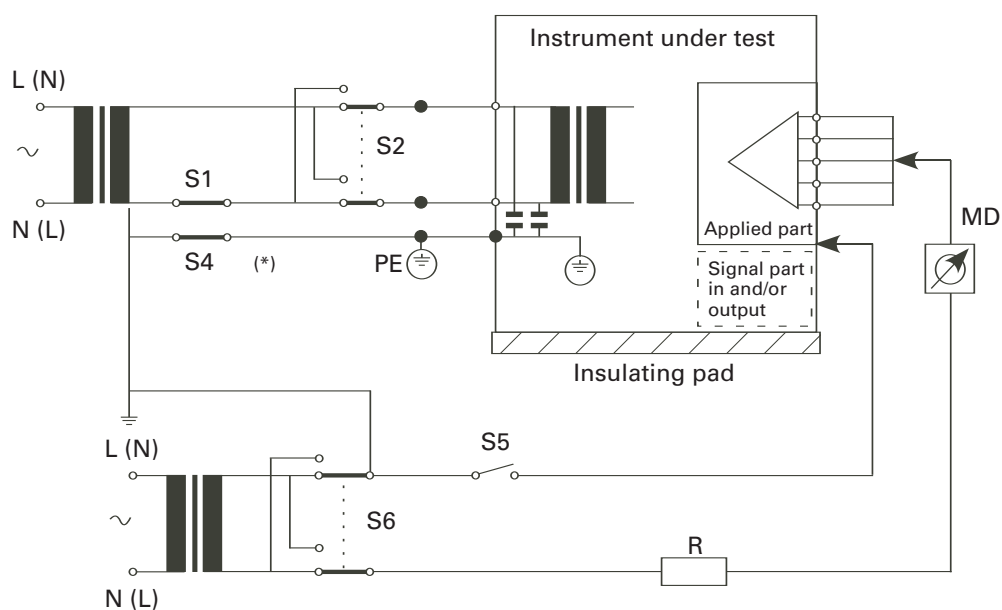
AC mains voltage is present on the applied part terminals during this test. Exercise caution to avoid electrical shock hazard.

Table 6-7. Safety Tests – Patient Leakage Current, with Mains Voltage on the Applied Part

Test or “Inspection” to Perform	Maximum Leakage Current
Patient Leakage Current - AC	$\leq 50 \mu\text{A}$ @ 250V (IEC601-1 or UL2601-1)
See “Safety Test Diagram - Patient Leakage Current - AC” on page 6-28	(Test at 110% of the nominal line voltage.)

**Test or Inspection to Perform**

(\*) Not present in Class 2



Measures patient leakage current from Applied Part to earth caused by external mains voltage on Applied Part with switch S5 open and closed. Each polarity combination possible is tested using S2 and S6

. Safety test according to EN60601-1 (Clause 19.4.h). Report largest value.

**Figure 6-5. Safety Test Diagram – Patient Leakage Current – AC**

# Troubleshooting

This chapter explains how to troubleshoot the monitor when problems arise. Tables are supplied that list possible monitor difficulties, along with probable causes, and recommended actions to correct the difficulty. Use this chapter when you suspect you have a problem with your monitor, or whenever you are referred to this chapter from another part of the Service Guide.

## 7.1 General Troubleshooting Safety Information

### WARNING



Do not attempt to troubleshoot the monitor if there is any sign of burning or smoking coming from the monitor. Call the Analogic Technical Support Services or your local Analogic representative immediately.

### Caution



Only qualified service personnel should open the monitor housing, remove and replace components, or make adjustments. If your medical facility does not have qualified service personnel, contact the Analogic Technical Support Services or your local Analogic representative.

## 7.2 Objectives

In order to meet this chapter's objectives, you should be able to diagnose and isolate hardware failures to the level of the "field replaceable part." In addition, this chapter describes how to troubleshoot problems using error codes.

This chapter is divided as follows:

**Part 1 Troubleshooting Checklist** – Provides checklist for hints and tips.

**Part 2 Solving Monitor Problems** – Provides the following:

- Tables listing monitor symptoms as well as causes and remedies.
- Techniques for troubleshooting the monitor before disassembling it.
- Checks to perform to isolate problems down to a specific replaceable part, for example, the power supply.

**Part 3 Using Support Functions** – Provides information on using error codes as a support feature.

## 7.3 Concepts

### Troubleshooting

This is the essential diagnostic step to be taken prior to any repair.

### Error Codes

These are the types of messages that generate and display to inform the user when the monitor has been unable to perform an operation.

## 7.4 Part 1 Troubleshooting Checklist

If any unit is not functioning properly, your first step is to restore factory settings. See *Restoring Factory Settings* on page 6-10 for additional information.



### Checks for Obvious Problems

When first troubleshooting the monitor, check for obvious problems by answering the following questions:

1. Is the monitor turned On?
2. Is the battery adequately charged?
3. If running from mains power supply, is the AC power cord connected to the monitor and plugged into an AC outlet?

### Checks Before Opening the Monitor

You can isolate many problems by observing indicators on the monitor before it is necessary to open the monitor.

Front Panel LED	Description
AC LED 	On: mains connected, battery charging Off: mains unplugged
Battery LED 	On: DC power on, monitor on Off: DC power off, monitor off

The following two steps are to make sure that the monitor's AC power supply and battery work correctly.

What to do if the monitor cannot be switched on, AC powered:

Step	Action
1	Ensure the battery has had ample time to charge (at least 15 minutes). A dead battery will prevent the monitor from powering On.
2	Check AC fuses in the AC receptacle.
3	The monitor should either be returned to the factory (see Section 14) or opened to isolate the defective component (see page 7-5).

What to do if the monitor cannot be switched on, battery powered:

Step	Action
1	Plug the monitor into an AC power source.
2	Ensure the battery has had ample time to charge (at least 15 minutes). A dead battery will prevent the monitor from powering On.
3	The monitor should either be returned to the factory (see Section 14) or opened to isolate the defective component (see page 7-5).

## 7.5 Part 2 Isolating and Solving Monitor Problems

### Technical Alarm Messages

The following table explains the technical alarm messages that the monitor can issue, and suggests a course of actions. When actions are numbered, always try them in the order given and only proceed to the next action if the current one is not successful in solving the problem.

Message	Cause of Failure	Remedy
"CO <sub>2</sub> Equip Malfunction"	Malfunction in the CO <sub>2</sub> hardware.	Verify failure and replace Extension with a known-good Extension.
"CO <sub>2</sub> No Tubing"	The FilterLine is disconnected, or an incorrect line is attached.	Attach a FilterLine. Remember that only Microstream accessories may be used with the monitor.
"CO <sub>2</sub> Sensor Warm-up"	The sensor has not reached operating temperature.	Allow the sensor to warm up.
"CO <sub>2</sub> Occlusion"	The FilterLine or exhaust tube is blocked to the extent that a measurement sample cannot be taken.  The outlet is occluded at Power On.  This message also appears after the Pump Op Time is reset.	Check the FilterLine and exhaust tube, then disconnect and reconnect the FilterLine. If the message is still displayed, use a new FilterLine.  If Pump Op Time has been reset, perform a flow check and store the flow in Service Mode (select "Store Flow").
"CO <sub>2</sub> Overrange"	The CO <sub>2</sub> value is outside the measurement range.	Refer to Operator's Manual, Section 18.
"CO <sub>2</sub> Purging"	The monitor is purging the FilterLine. This occurs when an occlusion is detected in the line or airway adapter. If the occlusion is not removed by purging, a "CO <sub>2</sub> Occlusion" message displays.	Check for an occlusion and remove. If necessary, replace the FilterLine.
"CO <sub>2</sub> Auto Zero"	An AutoZero is in progress. An AutoZero will be done at the following intervals: 5 minutes after connecting the FilterLine, 1 hour later, 12 hours later, and every 12 hours from there on.	None needed.
"ECG Leads Off"	Not all leads are connected.	Check the integrity of electrodes to ensure they are firmly attached. Make sure the ECG trunk cable is connected, the leads are connected to the electrodes, and the electrodes are attached. If the message still displays, use a new lead set.
"ICG Artifact"	Excessive patient movement.	Restrict patient movement and keep patient calm. Confirm that sensors are securely attached; check lead wires.
"ICG Leads Off"	One or more of the leads is not connected to the patient.	Make sure that the ICG patient cable is connected to the monitor and the patient leads, the leads are connected to the sensors and the sensors are firmly attached to the patient.
"Low ICG Amplitude"	Low or poor signal quality	Check the patient. Check the integrity of electrode, lead and cable connections. (See "ICG Leads Off.") Try to reposition the electrodes.
"Loss of Pulse from SpO <sub>2</sub> "	SpO <sub>2</sub> cannot find a pulse.	Make sure the SpO <sub>2</sub> patient cable is connected and the sensor is correctly attached to the patient. Try new location.

**Technical Alarm Messages (continued)**

Message	Cause of Failure	Remedy
"Low Battery"	The battery has less than 30 minutes of charge left.	Recharge the battery.
"NIBP - Artifact"	Incomplete measurement due to patient motion or physiology.	1. Check the patient. 2. Check cuff application and orientation.
"NIBP - Blocked Hose"	NIBP tubing blocked - measurement not possible.	Check that the tubing is not obstructed or pinched.
"NIBP - No Cuff"	Monitor unable to detect NIBP cuff.	1. Check to see that cuff is present. 2. Check cuff and tube connections for leaks.
"NIBP Overpressure"	This message appears when the NIBP cuff pressure increases above overpressure safety limits.	Remove the cuff from the patient. Make sure the rubber tube to the NIBP cuff is not kinked.
"NIBP - Time Out"	NIBP measurement took too long to complete	Check cuff placement and retry measurement.
"Recorder Out of Paper"	New paper needed.	Replace paper as instructed in the section titled <i>Recorder Paper Replacement</i> in the LIFEGARD II Operator's Manual.
"SpO <sub>2</sub> No Sensor"	Monitor cannot detect the SpO <sub>2</sub> cable or sensor.	Check that the SpO <sub>2</sub> patient cable is connected and the sensor is properly attached to the patient.
"SpO <sub>2</sub> Equip Malfunction"	SpO <sub>2</sub> hardware is faulty.	Verify failure and replace SpO <sub>2</sub> module. See Removing the SpO <sub>2</sub> Module on page 8-X.
"SpO <sub>2</sub> Weak Signal"	SpO <sub>2</sub> measurement is erratic.	1. Make sure the SpO <sub>2</sub> sensor is correctly placed. 2. If this does not solve the problem, make sure the sensor is working.
"SpO <sub>2</sub> Interference"	The level of ambient light is so high that the transducer cannot measure the pulse, or the cable is picking up interference.  Excessive patient movement is causing irregular pulse patterns.	1. Cover the SpO <sub>2</sub> sensor so that it does not get as much ambient light. 2. If this does not solve the problem, make sure the sensor cable is not damaged. 3. Try to reduce patient movement, or to relieve the cable strain on the sensor.
"SpO <sub>2</sub> Sensor Off"	Monitor does not detect SpO <sub>2</sub> sensor.	Make sure the SpO <sub>2</sub> sensor is connected.
"SpO <sub>2</sub> High Pulse Amplitude"	SpO <sub>2</sub> pulse amplitude too high for equipment.	Place sensor on another site.
"SpO <sub>2</sub> Non-Pulsatile"	Pulse is too weak or is not detectable, or the application site is too thin.	Change the application site of the sensor, or stimulate circulation at the current site.
"SpO <sub>2</sub> Sensor Malfunction"	Sensor is malfunctioning.	1. Change the SpO <sub>2</sub> sensor as soon as possible. 2. Return the faulty sensor to your biomedical department.
"Temperature Probe Disconnect"	Monitor is not detecting temperature reading.	Check that the temperature probe is properly connected to the monitor.



The following table can be used to solve problems that may occur in the monitor.

**Isolating the Defective Component**

Symptom	Cause of Failure	Remedy
The battery symbol is not displayed	A battery is not present in the monitor, the battery is defective, or there is a bad connection	Install a charged battery (see <i>Removing the Battery</i> on page 8-2. If a battery is already present, remove it and refit the battery making sure to push it completely into position. Check the connection wires to make sure wires are secured to the battery.
Some or all numerics or waves are not displayed.	Parameters are switched off. No accessories are connected.	Switch on parameters. Connect the required accessories. If connections are secure, replace the suspect accessory.
Monitor screen appears dim or brightness decreases from edge to edge.	Display backlight tube worn.	Replace backlight tube according to instructions in <i>Replacing the Backlight Tube</i> on page 8-5.
Monitor screen is not lit.	Display backlight tube worn or loose connection.  Main PCB module malfunction.	1. Check the backlight tube connector. 2. Replace the backlight tube.  Replace the Main PCB module according to instruction in <i>Removing the Main PCB Module</i> on page 8-8.
Monitor fails to power-up when the On/Standby button is pressed.	Battery is dead or monitor is not plugged in.  Keypad malfunction or keypad connector is loose.	Make sure the monitor is powered on by AC power. Check that the battery is adequately charged and AC power fuses are securely connected.  1. Check the keypad connector. 2. Replace the keypad according to the instructions in <i>Removing the Keypad on the Front Panel</i> on page 8-3.
No response when pressing the buttons on the front panel.	Keypad malfunction or keypad connector is loose.	1. Check the keypad connector. 2. Replace the keypad according to the instructions in <i>Removing the Keypad on the Front Panel</i> on page 8-3.
Audible alarm does not sound.	Speaker malfunction or speaker has a loose connector.  Main PCB module malfunction.	1. Check speaker connection. 2. Replace speaker according to the instructions in <i>Replacing the Speaker</i> on page 8-5.  Replace the Main PCB module according to the instructions in <i>Removing the Main PCB Module</i> on page 8-8.
Recorder is not printing.	Defective recorder.	Check that paper is installed properly and it is correct type, Analogic P/N AN4K-AC060.  Check that the recorder is correctly installed. If problem still exists, replace recorder according to the instructions in <i>Removing the Optional, External Recorder</i> on page 8-4.

*Isolating the Defective Component (continued)*

Symptom	Cause of Failure	Remedy
Recorder paper will not advance.	Paper is loaded incorrectly.  Defective recorder.	Replace paper as instructed in the section titled <i>Recorder Paper Replacement</i> in the LIFEGARD II Operator's Manual.  Check that the recorder is correctly installed and there is paper in the recorder. If problem still exists, replace recorder according to the instructions in <i>Removing the Optional Recorder</i> on page 8-4.
No sound from monitor.	Tone is switched off or low.	1. Turn the volume up by pressing the <b>Volume</b> button. 2. Power-cycle monitor. Tone should sound when monitor boots up. 3. Check cable connections to the speaker.
Incorrect Time Stamps Invalid data stored showing wrong times for data	The monitor's real-time clock is defective.  Real-time clock not set correctly.	Power the monitor On and then reset the time and date. See the LIFEGARD II Operator's Manual for instructions on how to set the date and time.
Cannot reprogram the time and date correctly.	Main PCB module malfunction.	Replace the Main PCB module according to the instructions in <i>Removing the Main PCB Module</i> on page 8-8.
No tone alarms  Speaker will not work.	Audible alarms are not switched on.  Cable disconnected.  Defective speaker.	Make sure audible alarms are switched on.  Reconnect cable.  Replace speaker.
The knob is rotated, no highlight appears on the display screen, and/or the monitor does not respond to wheel presses.	Main PCB module malfunction.	Replace the Main PCB module according to the instructions in <i>Removing the Main PCB Module</i> on page 8-8.

## 7.6 Part 3 Using Support Functions

When the monitor detects an error condition, the monitor shows an error code on the display screen. If such an error occurs during monitoring operation, an audible alarm tone also sounds. Press the Alarm Silence button to terminate the audible alarm tone.

When an error code appears on the display, a number in hexadecimal representation indicates the nature of the error. Additionally, Diagnostic Mode can be used to gain access to an error code record, stored in non-volatile memory, of the last 10 error codes encountered. See *Diagnostic Mode* in Chapter 6 for further details.

Each error code corresponds to a particular problem in the monitor. Recommended actions to take when an error code is encountered are listed below.

### Serviceable Hardware Error Codes

Hex Code	Explanation	Recommended Action
1	Improper shutdown	1. Power cycle 2. If this error persists, return the monitor to the Analogic Life Care Systems support group or your local Analogic representative.
4	The measured value for the 3.3V power supply is low.	1. Check the power supply. 2. Replace the power supply module.
5	The measured value for the 3.3V power supply is high.	1. Check the power supply. 2. Replace the power supply module.
8	The measured value for the 5V power supply is low.	1. Check the power supply. 2. Replace the power supply module.
9	The measured value for the 5V power supply is high.	1. Check the power supply. 2. Replace the power supply module.
E	A checksum error is detected on the power-up settings region of flash memory.	1. Turn power Off. 2. Turn power On while pressing both the Contrast and Volume buttons simultaneously. (See <i>Restoring Factory Settings</i> on page 6-XX. 3. All user selections must be restored. 4. If problem persists, replace main PCB module.
64	The SpO <sub>2</sub> module is sending an error message to the host CPU.	1. Ensure SpO <sub>2</sub> module is properly connected. 2. Replace the SpO <sub>2</sub> module. 3. If problem persists, replace main PCB module.
?	The CO <sub>2</sub> module is sending an error message to the host CPU.	1. Ensure Oridion module is properly connected. 2. Replace the Oridion module. 3. If problem persist, replace main PCB module.
65, 66	SpO <sub>2</sub> module has detected an error during initialization.	1. Replace SpO <sub>2</sub> module. 2. If problem persists, replace main PCB module.
6E-71	SpO <sub>2</sub> module has detected an error on its serial port.	1. Replace SpO <sub>2</sub> module. 2. If problem persists, replace main PCB module.

**Error Code Categories**

As a reference, the following table lists the general categories for other error codes. The error code categories are shown only in hexadecimal format. If unable to solve problem contact Analogic Life Care Systems technical support group.

Hexadecimal Code	Explanation
500xxx	internal user interface error
501xxx	remove serial port error
502xxx	date and time error
503xxx	NIBP error
504xxx	front end error
505xxx	alarm error
506xxx	audio error
507xxx	recorder error
508xxx	trend error
509xxx	flash memory data error
50axxx	SpO <sub>2</sub> error
50bxxx	ECG error
50cxxx	power-down task error
50dxxx	on-board diagnostic error
50exxx	power monitor error
50fxxx	temperature measurement error
510xxx	internal user interface error
511xxx	error handling error
513xxx	serial driver error
514xxx	system error
515xxx	CO <sub>2</sub> error

**Other Error Codes**

If an error code occurs that is not listed in the above sections, take the following actions:

Step	Action
1	Power cycle the monitor.
2	If the error code still displays, take the monitor out of service and contact the Analogic Life Care Systems support group or your local Analogic representative for advice on remedial action.
3	If the monitor powers up and the error code does not reoccur, enter the Diagnostic Mode and select the Error Code option. Examine the record of the last 10 error codes and determine if the same error code occurred previously.
4	If the Error Code screen indicates that the same error code has occurred previously, take the monitor out of service and contact the Analogic Life Care Systems support group or your local Analogic representative for advice on remedial action.
5	If the Error Code screen indicates no previous occurrences of this error, the monitor can be returned to service.

# Disassembly

This chapter provides step-by-step procedures that are used to access replaceable parts of the monitor. The sections in this chapter describe and photographically illustrate procedures for disassembling the monitor in order to remove or replace suspected defective assemblies or components.

## 8.1 Introduction

The monitor consists of two main assemblies, the front case assembly, and the rear case assembly.

All part numbers and exploded views of some assemblies are located in Chapter 9, *Spare Parts*. The monitor can be disassembled down to all major component parts, including:

- PCBs
- Battery
- Cables
- Function buttons
- Chassis enclosures

## 8.2 Tools Required

The following tools are necessary to disassemble the monitor.

- #1 and #2 Philips screwdrivers
- flathead screwdriver
- needle-nose pliers
- 5/8" socket wrench (for navigation wheel)
- 3/16" and 5/16" nut drivers
- 3/16" socket wrench.

---

### NOTE

During the disassembly procedure, some of the small parts may become lost and one, the Encoder bushing Adhesive Ring, is a single-use part and will be destroyed. It is strongly advised to purchase and have on hand, the Small Parts Kit, part number 10-64659-01 (see page 9-1) before starting the reassembly process.

---

### 8.3 *Disassembly Safety Information*

---

#### **WARNING**



Performance Verification: Do not place the monitor into operation after repair or maintenance has been performed, until all recommended Performance and Safety Tests listed in Chapter 5, *Testing the Monitor* of this Service Manual have been performed. Failure to perform all tests could result in erroneous monitor readings.

Before attempting to open or disassemble the monitor, disconnect the power supply from the monitor.

Before beginning any disassembly procedure, the battery must be removed.

High voltage is generated by the LCD backlight driver. Exercise caution when operating the monitor with the covers open.

---

#### **Caution**



Observe ESD (electrostatic discharge) precautions when working within the unit.

Before removing any module, be sure you are wearing ESD protection and you are working in a grounded environment.

If the internal battery cable has been disconnected, pay particular attention to the polarity of the cable before reattaching. If the battery cable polarity is reversed, it is likely that circuit damage will occur.

---

### 8.4 *Disassembly Procedures*

This section provides instructions for closed case, front case and rear case disassembly procedures.

#### **8.4.1 Closed Case Disassembly Procedures**

This section describes the items that can be removed without disassembling the main case of the monitor.

##### ***Removing the Battery***



---

#### **WARNING**



Before beginning any disassembly procedures, the battery must be removed.

---

Step	Action
1	<p>With the rear of the monitor facing you, disconnect the battery cover from the rear panel using a Philips no. 1 screwdriver to loosen the 4 captive screws fastening the battery cover.</p> 
2	Slide the battery out by tilting the monitor towards you.
3	Disconnect both battery lug terminals to release the battery.
4	<p>When you re-insert the battery, verify that the battery is inserted the correct way and the polarity is correct (see figure below).</p> 


#### *Removing the Navigation Wheel*

Step	Action
1	Firmly grasp both sides of the wheel and pull straight back from the monitor. The wheel should slip off the encoder shaft.
2	For further disassembly, use the 5/8" socket wrench to unscrew the brass bushing.



#### **NOTE**

The brass bushing adheres to the front case by an adhesive ring, the Encoder Bushing Adhesive Ring. This ring is a single-use part that will become damaged during removal. It is strongly advised to purchase and have on hand, the Small Parts Kit, part number 10-64659-01 (see page 9-1) before starting the reassembly process.

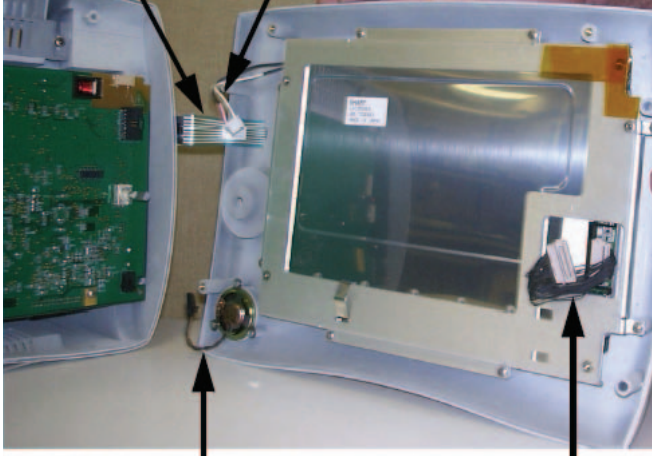
*Removing the Recorder (Models AN43XP only)*

Step	Action
1	Press the external Paper Eject button on the right hand side of the recorder. The door drops forward.
2	Remove the paper roll. Two captive screws are visible on the back panel of the recorder.
3	Use a Philips #2 screwdriver to loosen the two captive screws. 
4	Pull the recorder straight out of the side of the monitor by placing your index and middle fingers in the inside center of the recorder and firmly pulling the recorder toward you.

*Separating the Front from the Rear Case*

Step	Action
1	Verify that the battery has been removed. If not, see <i>Removing the Battery</i> on page 8-3.
2	Verify that the navigation wheel and brass bushing have been removed. If not, see <i>Removing the Navigation Wheel</i> on page 8-3.
3	Use a Philips #2 screwdriver to remove the 6 screws fastening the Rear Case Assembly to the Front Case Assembly.  <div data-bbox="941 1318 1364 1486"> <p><b>NOTE</b></p> <p>The top 2 screws adjacent to the handle are 1/2" long and the 4 remaining screws are 1" long.</p> </div>
4	Facing the front of the monitor, shift the front case slightly to the right, making sure that you do not break off the navigation wheel's encoder shaft. 



Step	Action
5	<p>Disconnect the display cable located on your left-hand side by pulling the connector towards you. Disconnect the backlight, keypad and speaker cable located on your right-hand side.</p> <p>Keypad Cables      Backlight Cable</p>  <p>Speaker Cable      Display Cable</p>
6	Separate the front from the rear case.

#### *Front Case Disassembly*

After you have separated the front from the rear case you can replace the following from the front case assembly:


- Keypad
- Speaker
- Backlight Tube
- Display, LCD and associated items

#### **Caution**




Before you disconnect or remove any module, make sure you are wearing EDS protection and you are working in a grounded environment.

#### *Removing the Keypad on the Front Case*



Step	Action
1	The keypad is attached with an adhesive to the front case. To remove it, carefully lift up one corner of the keypad with a flathead screwdriver.
2	<p>Peel the adhesive away from the front case.</p> 

*Replacing the Speaker*

Step	Action
1	Use a Philips #1 screwdriver to remove the 3 screws and flat washer fastening the speaker. 
2	Pull the speaker up.

*Replacing the Backlight Tube*

The backlight tube is located within the LCD screen. However, you do not need to disassemble the LCD screen display to replace the backlight tube.

Step	Action
1	Insert a small, thin, flathead screwdriver into the crevice between the LCD screen and where the backlight tube slides in. 
2	Using the screwdriver, grab the corner of the backlight tube and gently pull the tube out. Re-insert a new backlight tube. 

*Rear Case Disassembly*


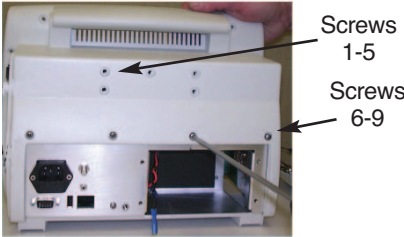

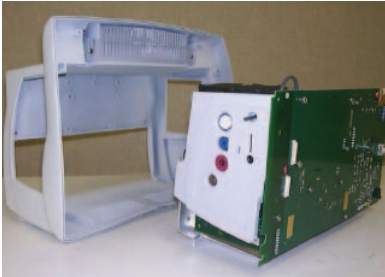
You must disassemble the rear case to remove the following modules:

- Main PCB
- Patient Monitoring I/O
- SpO<sub>2</sub>
- CO<sub>2</sub>
- NIBP
- Communications
- Power Supply

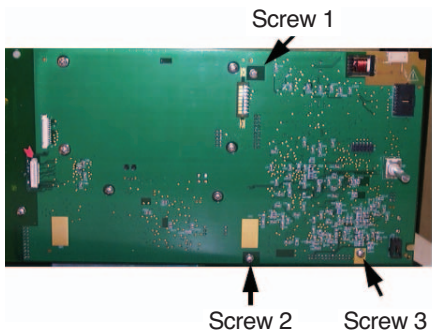
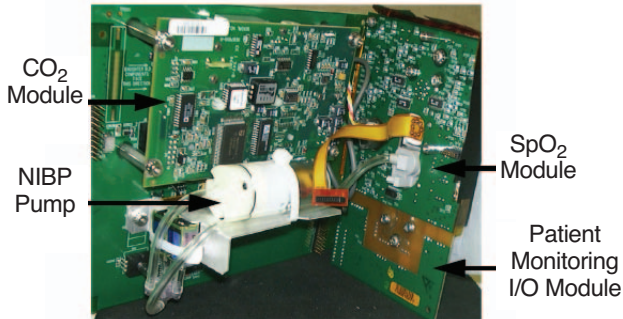
**Caution**

Before you remove any module, make sure you are wearing ESD protection and you are working in a grounded environment.

To disassemble the rear case:

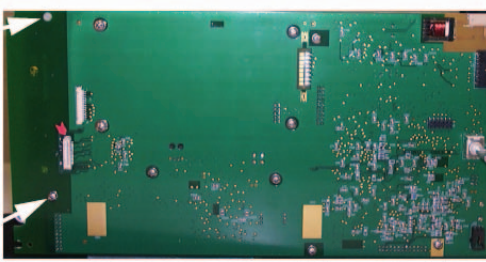
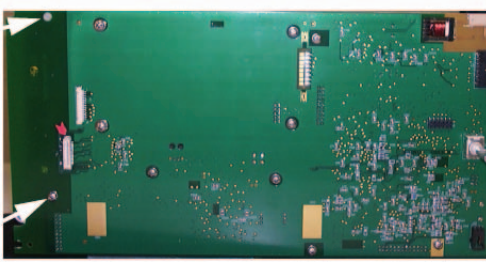
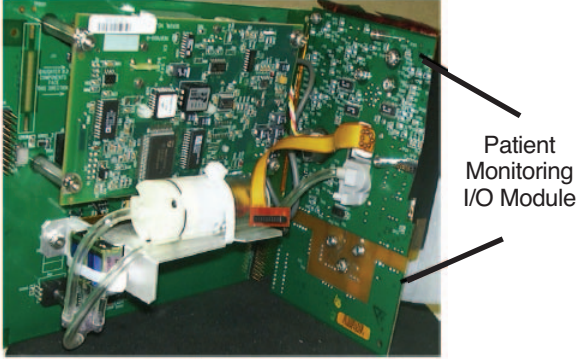
Step	Action
1	Verify that the battery has been removed. If not, see <i>Removing the Battery</i> on page 8-X.
2	Verify that the recorder has been removed. If not, see <i>Removing the External Recorder</i> on page 8-X. If there is no recorder, unsnap the recorder door using a flat-head screwdriver (see figure below). 
3	Use a Philips no. 2 screwdriver to remove the 9 screws fastening the rear case. 
4	Remove the two screws located in the bottom corners of the rear case. 
5	Gently slide the chassis away from the rear case. 

*Removing the Main PCB Module*

Step	Action
1	<p>Unscrew the PCB module by loosening the following 3 screws:</p> 
2	<p>Gently pull the module towards you.</p>
3	<p>After you have removed the Main PCB module, you should have access to the CO<sub>2</sub>, SpO<sub>2</sub>, NIBP pump, and the Patient Monitoring I/O modules.</p> 

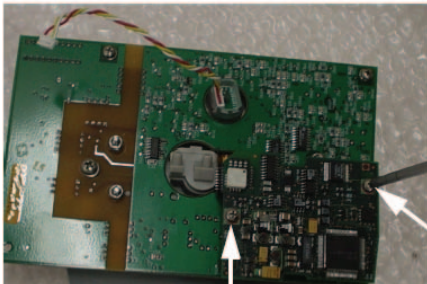
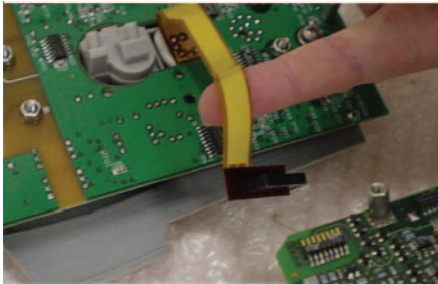
***Removing the Patient Monitoring I/O Module***

Follow these instructions for removing the I/O module from the Main PCB module.

Step	Action
1	<p>Remove the following 2 screws to remove the connector module.</p> <p>Screw 1 </p> <p>Screw 2 </p> <p><i>Note — Use a flathead screwdriver to remove Screw 1.</i></p>
2	<p>Slide the I/O module out.</p>
3	<p>Disconnect the CO<sub>2</sub> connector and tubing and the NIBP tubing. Slide the CO<sub>2</sub> exhaust tubing out.</p>
4	<p>Pull the I/O module away.</p> 

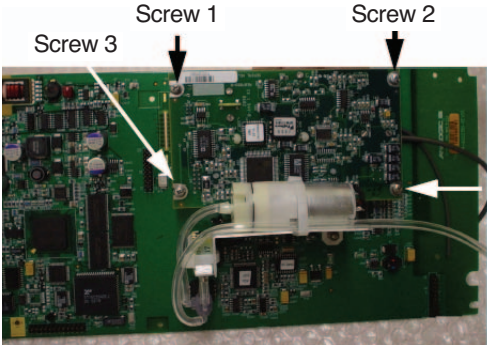
***Removing the SpO<sub>2</sub> Module***

After you have removed the Patient Monitoring I/O module from the Main PCB module, you can remove the SpO<sub>2</sub> module. To do this:

Step	Action
1	Remove the 2 screws fastening the SpO <sub>2</sub> module to the I/O module.  <p>Screw 1      Screw 2</p>
2	Remove the connector that attaches the SpO <sub>2</sub> module to the I/O module. 
3	Gently pull the SpO <sub>2</sub> module away.

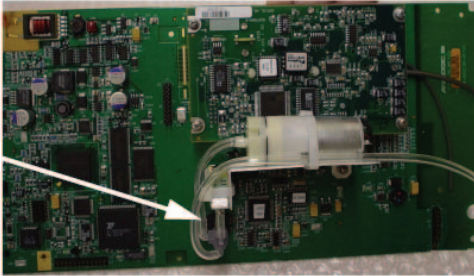

***Removing the CO<sub>2</sub> Module*****NOTE**

This procedure is only for Models AN4321P and AN4323P.

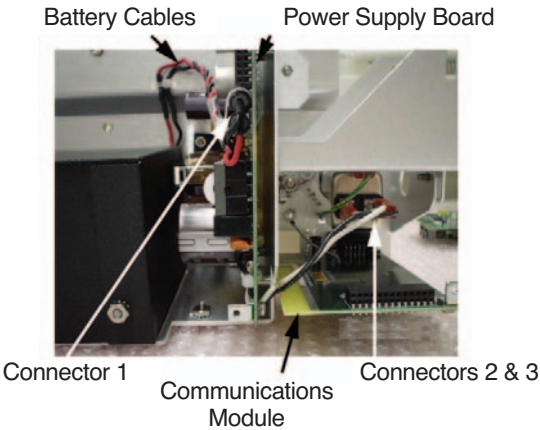
Step	Action
1	Remove the 4 screws on the CO <sub>2</sub> module.  <p>Screw 1      Screw 2 Screw 3      Screw 4</p>
2	Tilt the CO <sub>2</sub> module towards the NIBP pump.
3	Gently pull the module away from the Main PCB module. <p><i>Note — When reassembling the CO<sub>2</sub> module, ensure that the CO<sub>2</sub> header matches up with the mating header.</i></p>



*Removing the NIBP Pump*

Step	Action
1	Remove the connector from the NIBP pump.  
2	Cut the tie wrap.  

*Removing the Power Supply Module*

Step	Action
1	Use the needle-nose pliers to unplug the three connectors.  
2	Remove the two screws that connect the power supply to the rear panel.
3	Remove the screws on the side and bottom of the rear panel.
4	Cut the tie wrap that holds the battery cables together.
5	Use a 5/16 nut driver to unfasten the power supply from the rear panel.
6	Pull the power supply module away from the rear panel.

# Spare Parts

Spare parts are listed in the tables that follow.

## 9.1 Small Parts Kit

Most small parts and hardware can be found in the Small Parts Kit, Part Number 10-64659-01. The table below call out the contents.

Quantity	Description
1	Gasket, EMI/RFI, double-sided contact strip
1	Ground strap, RFI, 3" x 0.5" (7.62 mm x 1.27 mm)
1	Encoder bushing, locking ring
1	Cable tie
4	Machine screw, PHCR, 4-40 x 1/4 SS
2	Machine screw, PHCR, 6-32 x 1/4 SS
10	Machine screw, PHCR, 6-32 x 3/8 SS
4	Machine screw, PHCR, 6-32 x 1/2 SS
2	Machine screw, PHCR, 6-32 x 1 SS
5	Machine screw, M4X 16 DIN7985 SS
4	Washer, FL NO. 4 SS
5	M Washer, M4 DIN6798A SS
3	Nut, KEPS 6-32 SS

## 9.2 LIFEGARD II Top Level Assembly

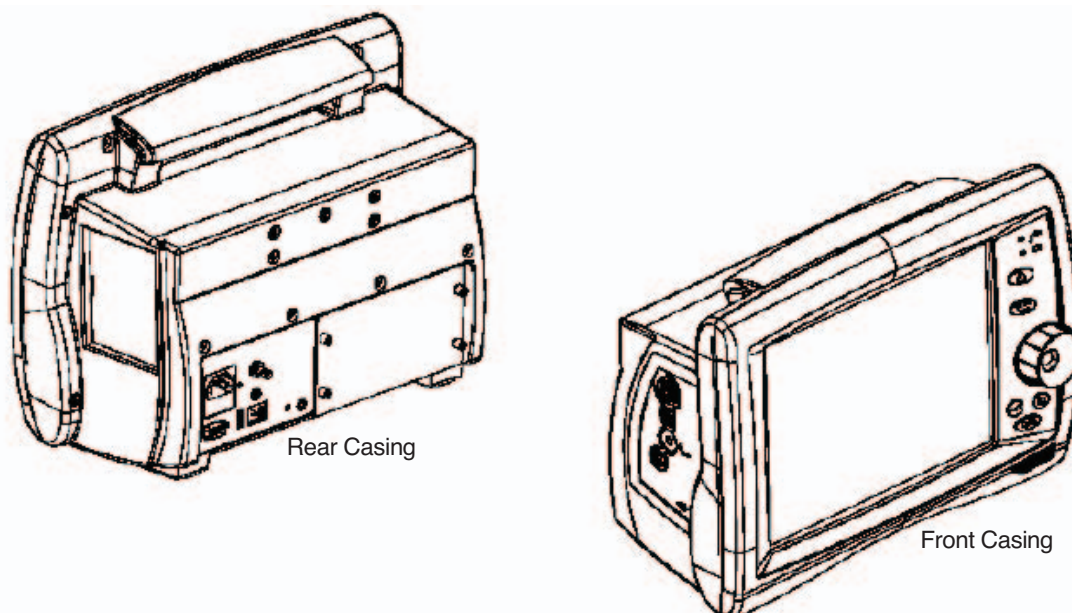


Figure 9-1.



### 9.3 Front Panel Assembly

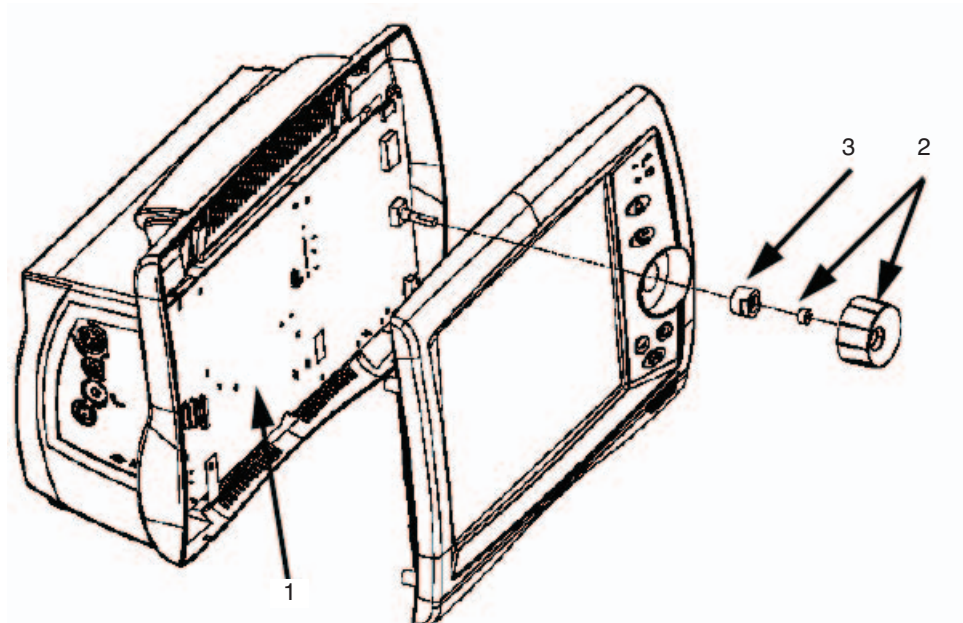


Figure 9-2. (1 of 2)

Item No.	Part Number	Description	Page Ref. for Disassembly
1	10-60023S-03	Main PC Board	page 8-8
2	10-64708-01	Navigation Knob and Retainer Spring	page 8-3
3	10-64660-01	Navigation knob bushing (part of front case components)	page 8-3

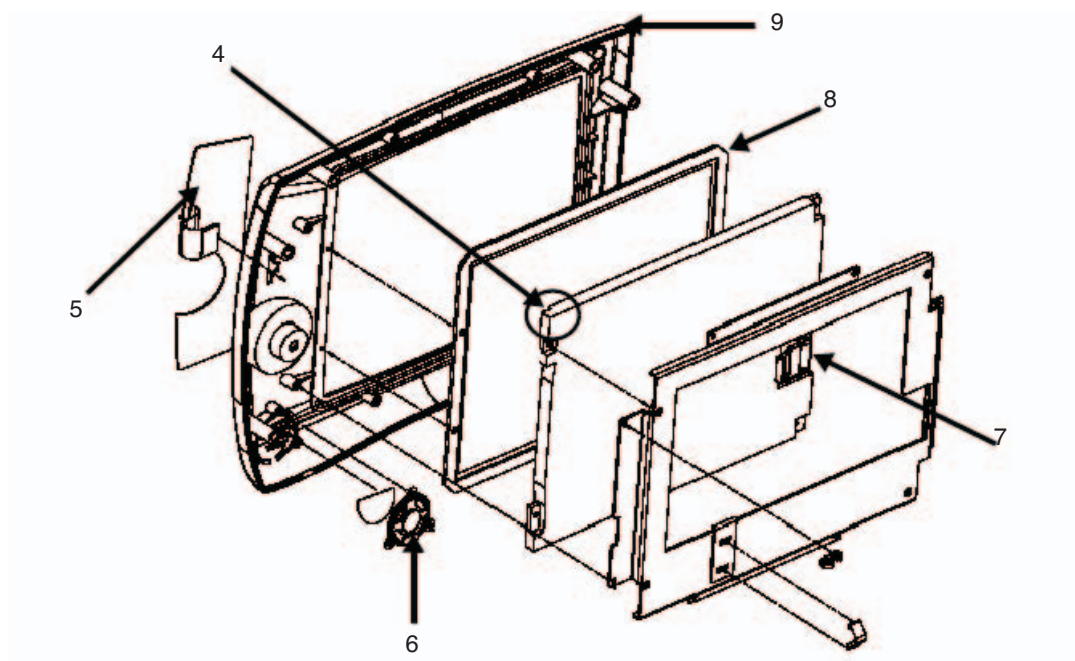


Figure 9-3. (2 of 2)

Item No.	Part Number	Description	Page Ref. for Disassembly
4	10-64655-01	Backlight Tube	page 8-6
5	10-64707-01	Keypad	page 8-3
6	10-64660-01	Speaker (including speaker cable) (See front case kit components, page 9-4)	page 8-5
7	10-64654-01	Display Cables (See display kit components, page 9-4)	page 8-5
8	10-64660-01	Bezel Protective Window Display (See front case kit components, page 9-4)	No Disassembly Procedure
9	10-64660-01	Front Housing (See front case kit components, page 9-4)	No Disassembly Procedure

## 9.4 Front Case Kit

The Front Case Kit, 10-64660-01, contains all the parts that comprise the front case or bezel except for the LCD display. The table below calls out the contents.

Order: 10-64660-01, Front Case Kit.

Quantity	Description
1	Front case, molded, printed
1	Display window
1	LCD display bracket
1	Keypad
1	Navigation knob, molded, with retainer ring
1	Navigation knob bushing
1	Encoder bushing
1	Speaker cable assembly
1	Speaker mesh grill
1	Cable tie
10	Machine screw, SEMS, PHCR 4-40 x 1/4 SS
5	Machine screw, SEMS, PHCR 4-40 x 3/8 SS
4	Washer, FL No. 4 SS
3	Washer, No. 4, 0.375 OD TYP B RGLR S
1	Adhesive, instant, cyanoacrylate, clear

## 9.5 Display Kit

The Display Kit, 10-64654-01, contains all the parts required to replace the LCD display. The table below call out the contents. Order: 10-64654-01, Display Kit.

Quantity	Description
1	Display, LCD, color, 640 x 480, 10.4 in.
1	Foam pad, 1/8 x 0.5 x 1.0 in.
1	Display cable assembly (Note)
2	Display connector pads

Note: Display cable can be ordered separately. Order: 10-64709-01, Display Cable.

## 9.6 Rear Panel Assembly

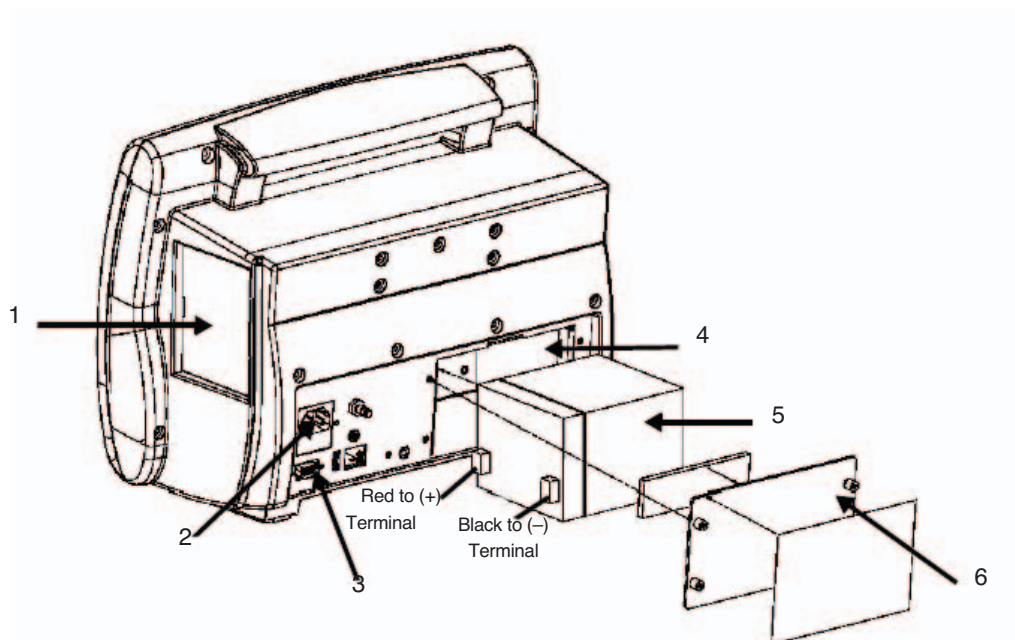


Figure 9-4. (1 of 3)

Item No.	Part Number	Description	Page Ref. for Disassembly
1	10-64664-01	Recorder Blanking Plate	8-4
1a	10-64656-01	Recorder	8-4
2	10-64658-01	AC Connector, Power Entry Module with Fuses	No Procedure Displayed
3	—	RS-232 Port (Part of Communication Board) (see page 9-5)	No Procedure Displayed
4	—	Battery Housing (Contained in Chassis Kit) (see page 9-6)	8-3
5	10-64657-01	Battery	8-3
6	—	Battery Cover (Contained in Chassis Kit) (see page 9-6)	8-3

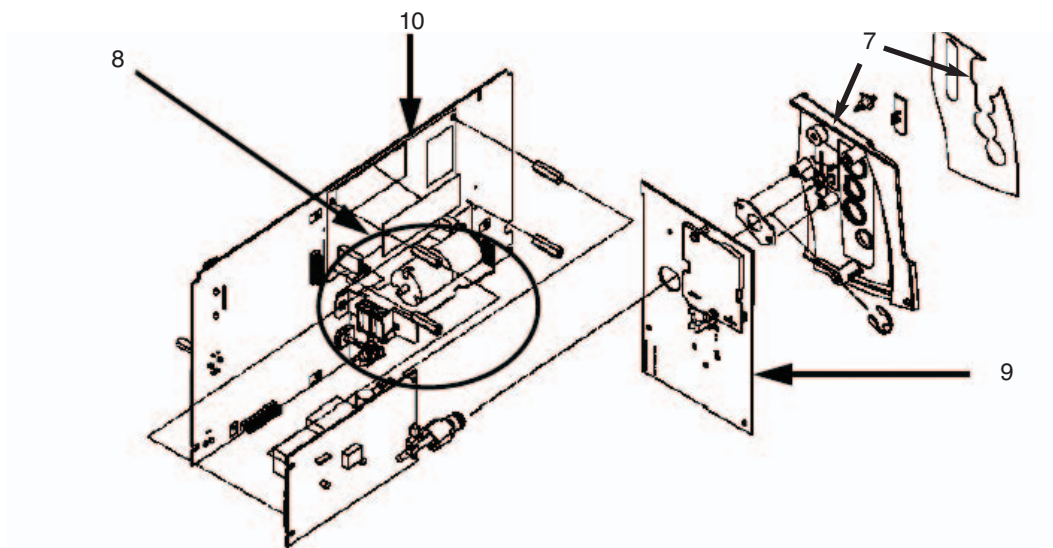


Figure 9-5 (2 of 3)

Item No.	Part Number	Description	Page Ref. for Disassembly
7	10-64663-01	Side Panel w/label for AN4320/AN4320P	8-8 & 8-9
	10-64663-02	Side Panel w/label for AN4321P	
	10-64663-03	Side Panel w/label for AN4322P	
	10-64663-04	Side Panel w/label for AN4323P	
8	10-64653-01	NIBP Assembly Components	8-11
9	10-63600S-01	Patient I/O Module	8-9
10	10-63601S-01	Patient Daughterboard Assembly	No Procedure Displayed
11	10-43248S	Power Supply Assembly	8-11
Not Shown	10-60192S-03	Communication Board	8-11

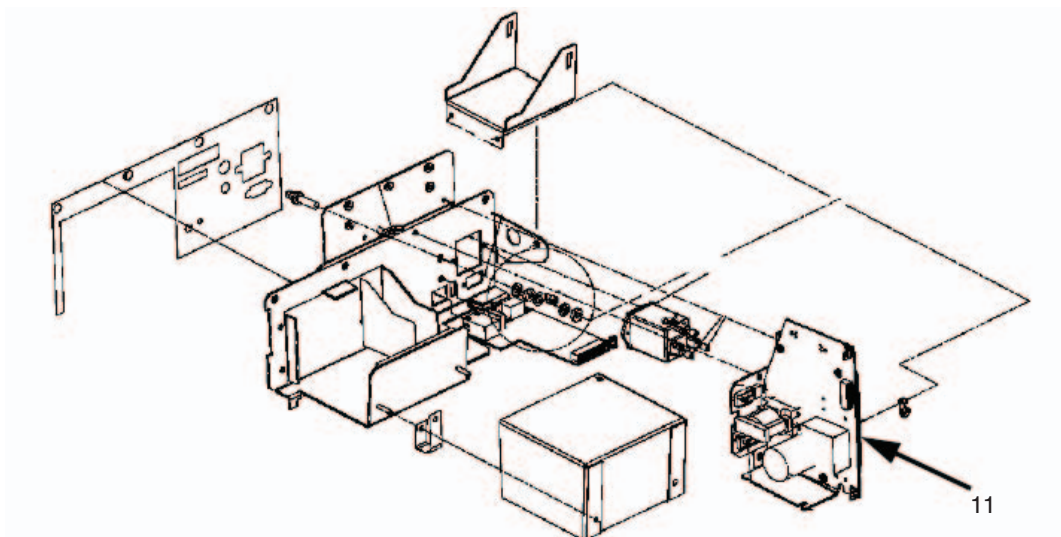


Figure 9-6 (3 of 3)

### 9.7 **Rear Case Kit**

The Rear Case Kit, 10-64661-01, contains all the parts that comprise the rear case. The table below calls out the contents. Order: 10-64661-01, Rear Case Kit.

Quantity	Description
1	Rear case, molded
1	Handle vent, molded
1	Gasket, silicone, 0.07 in. D x 34 in. L
2	Foot pads
2	Machine screw, SEMS, PHCR 6-32 x 3/8 SS

### 9.8 **Chassis Case Kit**

The Chassis Kit, 10-64662-01, contains all the parts associated with the main chassis. The table below call out the contents. Order: 10-64662-01, Chassis Kit.

Quantity	Description
1	Rear label
1	Rear chassis
1	Battery door
1	Battery housing
2	Battery door pads
1	Battery insulator
1	Battery door label
1	Ground plug
2	M Washer M6 DIN6798J BR/NP
2	M nut M6 DIN439B SS

### 9.9 **Additional Spare Modules**

Part Number	Description	Page Ref. for Disassembly
10-64651-01	SpO <sub>2</sub> Module	page 8-10
10-64652-01	CO <sub>2</sub> Module (for AN4321P/AN4323P)	page 8-10

# Packing for Shipment

This chapter explains how to pack the monitor for shipment.

## 10.1 General Instructions

To pack the monitor for return, disconnect all cables. It is not necessary to return sensors, patient cables, NIBP tubing and cuff or power cord. Pack the monitor carefully. Failure to follow the instructions in this section can result in loss or damage not covered by the warranty. If the original shipping carton is not available, use another suitable carton.

Prior to shipping the monitor, contact the Analogic Life Care Systems Support Group for a Returned Material Authorization (RMA) number. mark the shipping carton and any shipping documents with the RMA number.

## 10.2 Repacking the Original Carton

If available, use the original carton and packing materials. Pack the monitor as follows:

Step	Action
1	Place the monitor, and if necessary, accessory items in original packaging.
2	Close the shipping carton and seal with packaging tape.
3	Label carton with shipping address, return address and RMA number, if applicable.

## 10.3 Repacking in a Different Carton

If the original carton is not available, use the following procedure to pack the monitor.

Step	Action
1	Place the monitor in a plastic bag.
2	Locate a corrugated cardboard shipping carton with at least 200 pounds per square inch (psi) bursting strength.
3	Fill the bottom of the carton with at least 2 inches of packing material.
4	Place the bagged unit on the layer of packing material and fill the box completely with packing material.
5	Seal the carton with packing tape.
6	Label carton with shipping address, return address and RMA number, if applicable.



# RS-232 Interface

This chapter explains how to properly use and connect the RS-232 interface and cables.

## 11.1 General RS-232 Safety Information

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### WARNING



Do not place the monitor in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient connections because disconnection could then result in the monitor dropping on the patient.

---

### WARNING



If you connect the monitor to any instrument, verify proper operation before clinical use. Refer to the device's manual for full instructions.

Accessory equipment connected to the monitor's data interface must be certified according to IEC Standard 950 for data processing equipment or IEC Standard 60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC Standard 60601-1 system requirements.

Anyone who connects additional equipment to the signal import port or signal output port configures a medical system and is, therefore, responsible to ensure that the system complies with the requirements of IEC Standard 60601-1-1. If in doubt, consult with the Analogic Life Care Systems Support Group or your local Analogic representative.

---

### Caution



Connection to a battery operated PC should only be allowed by the end user.

Connection to a line powered device with an ITE Class II power supply is acceptable provided it passes all 60601-1-1 tests without a problem.

If there is a line powered device with a Class I power supply, such as a line powered PC or a printer in the system, there must be either optical isolation of the data cable or the Class I devices must have isolated transformers.

---

### NOTE

The monitor and its accessories must be tested by qualified service personnel at regular intervals to verify proper operation, according to the procedures of the user's institution. Additional important safety information can be found in the LIFEGARD II Operator's Manual.

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## 11.2 The RS-232 Interface

The RS-232 interface enables you to:

- send a nurse call signal
- export trend data to an external PC

### Cable Connections

A 9-pin connector mounted on the rear panel provides the access port for the serial (RS-232) interface to a suitably configured personal computer. Or, alternatively, qualified service personnel can use the connector to send a Nurse Call signal. The following figure shows the location of the RS-232 interface on the monitor.

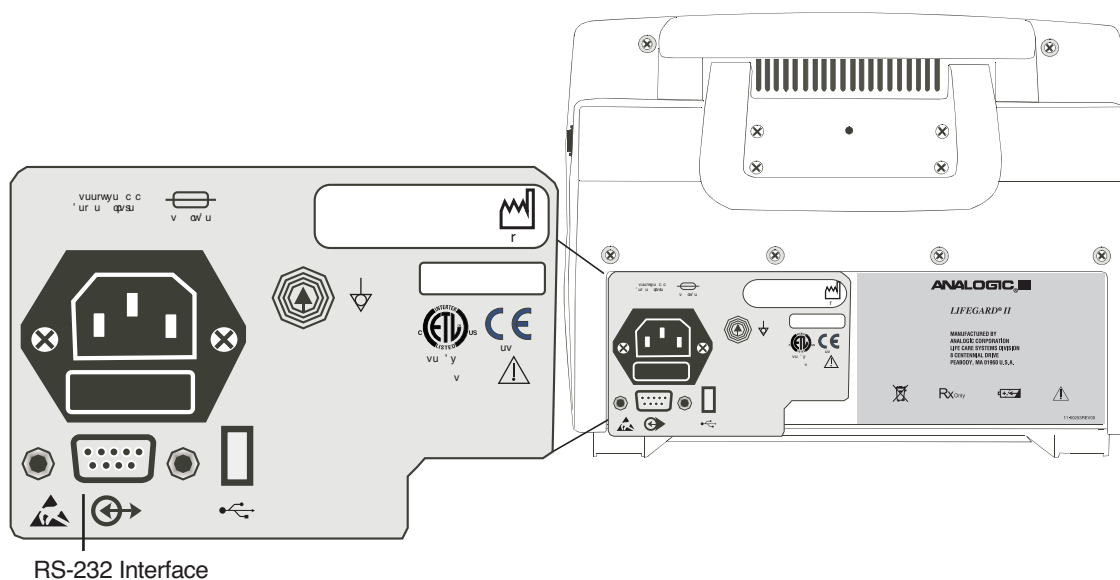


Figure 11-1. RS-232 Interface

Pin connections for the 9-pin connector are as follows:

Pin #	Signal	Direction
1	not used	
2	Rx data	input
3	Tx data	output
4	DTR	output
5	Signal Ground	input/output
6	DSR	input
7	RTS	output
8	CTS	input
9	Alarm Out	output

### ***Nurse-Call***

Pin 9 of the RS-232 serial interface connector provides an Alarm Out signal. Any time there is any alarm condition active in the monitor, and if the Nurse Call Signal option in the **Setup Menu** is On, pin 9 goes to plus RS-232 level voltage ( $> +5$  VDC). The alarm delay shall be  $< 0.5$  seconds.

If in the **Setup Menu**, the Nurse Call Signal option is Off, pin 9 is always at the minus RS-232 level voltage ( $< -5$  VDC). In order to make use of the Alarm Out signal, pin 9 should be connected to a high-impedance circuit ( $> 1000\Omega$ ) and protected against transient voltages.



# Theory of Operation and System Architecture

## 12.1 *General*

This section contains an overview of the theory of operation of the major functional modules of the monitor. Analogic service providers that perform bench repair at the assembly level should review this high level information.

Please be aware that Analogic Life Care Systems Support Group only stocks assembly level parts. Analogic does not recommend making changes.

## 12.2 *System Overview*

The monitor is a full function monitor for use on adult and pediatric patients.

The functions performed by the system include monitoring patient ECG, heart rate, respiration rate, blood pressure, blood oxygen saturation, and temperature. Optional functions could include CO<sub>2</sub> and ICG.

In addition to monitoring and displaying the status of these physiological parameters, the instrument performs various microprocessor-programmed analytical functions such as:

- Creating both visual and audible alarm signals when set limits are violated.
- Creating and displaying warning messages when conditions are detected that would degrade or prevent valid measurements.
- Creating and displaying trend waveforms or tabular data.
- Providing input to an optional recorder for printout of current or trend waveforms or tabular data.

The monitor is essentially a battery-powered instrument. An internal charging unit is designed to accept an external AC line voltage. The charger uses the external power source to maintain a “float” voltage source available to the battery.

## 12.3 *Block Diagram*

The functions are represented graphically in the following figure. Each section of the System Block Diagram is described briefly in the text that follows the illustration. This is followed by more detailed descriptions of the theory of operation of each block.

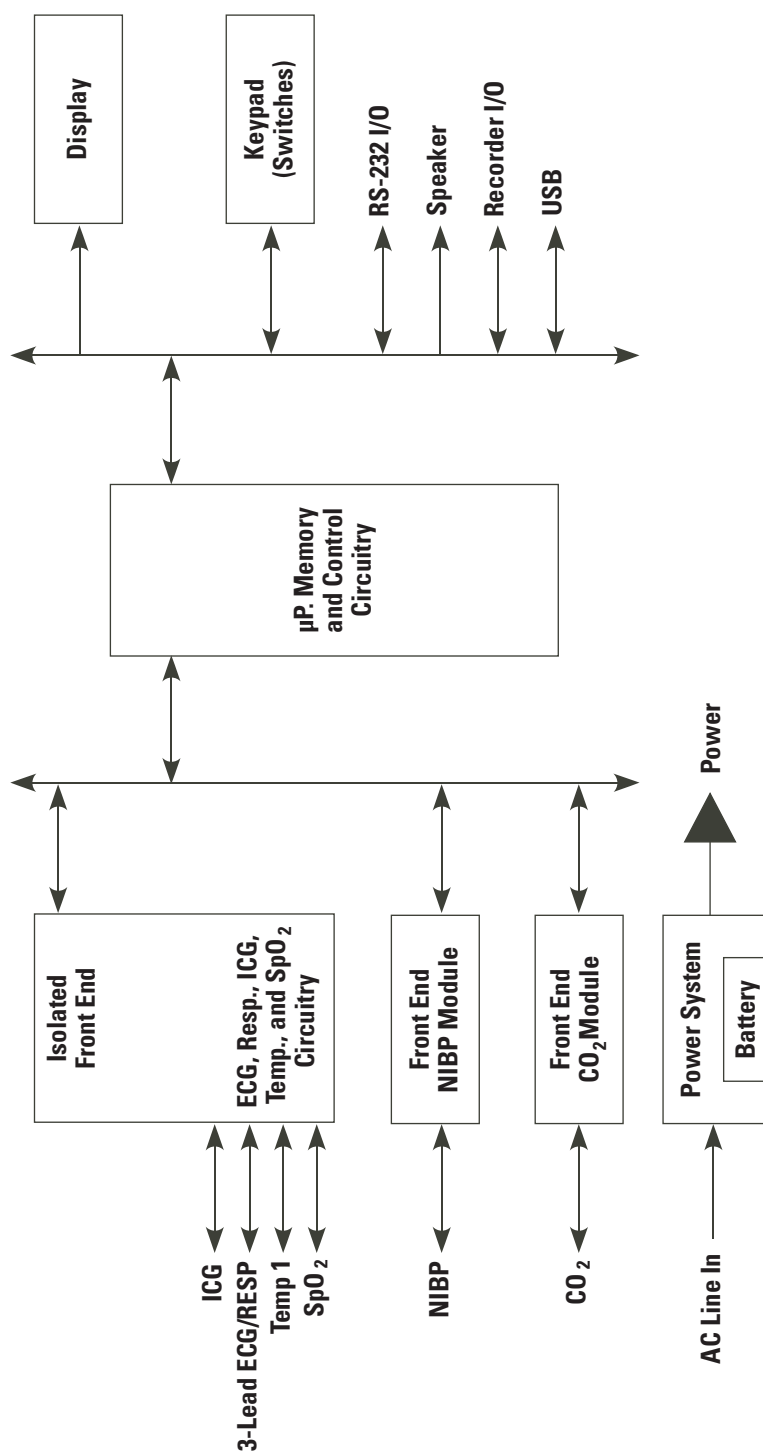


Figure 12-1. System Block Diagram

## **12.4      *Isolated Front End***

The Isolated Front End section includes all of the circuitry to convert ECG, ICG, SpO<sub>2</sub>, and Temperature measurements to digital format; and to connect this information to the processor. The Respiration detection is obtained from two of the three electrodes of the ECG connections.

## **12.5      *NIBP Front End***

The NIBP section contains the pumps, valves, pressure measurement circuitry, and control circuitry for the non-invasive blood pressure measurement. Pressure data is converted to digital format and conveyed to the processor section.

## **12.6      *Power System***

The power system section contains a power supply capable of operating the monitor and charging the battery from an AC source of 100 to 240 VAC at 50 to 60 Hz. The battery provides the operating power.

## **12.7      *Microprocessor, Memory and Control***

The Microprocessor, Memory and Control section contains the system CPU and all digital support circuitry. The latter includes the RAM, non-volatile memory, and real-time clock. This section also contains the display logic, keypad (switch) interface logic, RS-232 I/O control, USB, and printer logic.

## **12.8      *Display***

The display is a TFT (color), backlit fluorescent LCD unit. The active screen size is 8.3 x 6.2 in (210.8 x 157.5 mm): 10.4 in (264.2 mm) diagonally, and the resolution is 640 x 480 pixels.

## **12.9      *Keypad***

The keypad circuit contains five pushbutton membrane switches and two green LEDs. The LEDs are driven by the power supply system and indicate the power source.

The **On/Standby** button, connected directly to the power supply, toggles the power between On and Standby modes. When in Standby, the display is blank, and no monitoring is performed. However, the batteries are charging if an AC source is connected to the rear panel.

The **Audio Alarm Control** button is connected directly to the processor and to the system power supply. Response of the processor depends upon the action in pressing this button. If momentarily pressed (less than 2 seconds), alarms are paused temporarily for a preset interval determined by the menu selection. If pressed twice within 10 seconds, the alarm sounding for a specific parameter is silenced temporarily for a preset interval determined by the menu selection. Other alarms, not related to this parameter, can still sound during this period. If pressed and held for 2 seconds or more, the Audio Off condition is initiated.

The NIBP button is connected to the processor. Response of the processor depends upon the state of NIBP operation at the time and the action in pressing this button. If momentarily pressed, (less than 2 seconds), a single NIBP measurement is obtained. If pressed for 2 seconds or more, the processor initiates a STAT monitoring sequence. Pressing the NIBP switch at any time a pressure measurement is in effect causes the processor to terminate the measurement and to deflate the cuff.

The **Contrast** button operates in conjunction with the navigation wheel to determine the apparent contrast setting in the display. Changing the contrast is a change in the viewing angle. Outputs of the button and wheel are connected to the processor.

Momentarily pressing the button changes the color of the background from A to B, factory-default value.

Momentarily pressing the button followed within 3 seconds by a rotation of the wheel enables varying the contrast of the display. When there has been no wheel rotation for 3 seconds, the contrast control function is terminated by the processor. The contrast control function is also terminated if the wheel is pressed at any time within this 3 second interval.

The **Volume** button operates in conjunction with the navigation wheel to determine the volume of the heart rate audible tone. Pressing this button enables the wheel to vary the tone volume.

### **12.10    *Navigation Wheel***

This is a rotating, push-switch wheel. The associated wheel circuitry generates a pulse when pressed and generates a digitally encoded pair of quadrature signals whose relative magnitudes and polarities represent the angular position of the wheel. These outputs are connected to the processor where they are interpreted as required for the functions involved. Successive angular positions determine the direction of wheel rotation.

In addition to the functions performed when in conjunction with the keypad as described above, the wheel operates in conjunction with the display to select menus and lists of parameter variables.

### **12.11    *RS-232 I/O***

This is a rear panel 9-pin connector providing interfaces with other computer systems or equipment. The driver for this “port” is a Universal Asynchronous Receive-Transmit (UART) integrated circuit that interfaces this port with the microprocessor. The baud rate for this serial transmission function is programmable from 1200 baud to 38.4 kilobaud.

Pin number 9 of the RS-232 connector is reserved for a Nurse Call signal. The nurse call signal reacts when a low, medium, or high level alarm is activated.

### **12.12    *Speaker***

The speaker is capable of providing 73 dBA of volume at a distance of one meter during alarm conditions. The processor drives the speaker in different patterns as specified for the different alarm priorities and conditions. Refer to the LIFEGARD II Operator’s Manual for descriptions of alarm responses.

### **12.13    *USB Printer Interface***

The AN4300 acts as a USB host, supporting USB Rev 1.1. Only USB printers are supported by the USB port.

## 12.14 **Recorder**

The optional recorder module is installed in the right panel of the monitor. Refer to the LIFEGARD II Operator's Manual for printing procedures. It provides users with the capability to obtain hardcopy records of selected vital sign information.

Basic control of the recorder is implemented by two pushbutton controls on the recorder's front panel. The Continuous button is used to obtain continuous recordings of the real-time waveforms displayed in the top two graphic frames. Along with the waveforms, the recorder prints the values of the vital signs being displayed. The printing continues until the user presses either recorder button a second time.

The Snapshot button initiates a snapshot printout for 20 seconds of the same information recorded by the continuous control.

If scrolling is enabled in a display frame containing trend data when the Continuous button is operated, then the trend record for that vital sign is printed. If the Snapshot button is operated, then only the trend data on the display is printed.

The recorder may be programmed via the monitor menu display to print a snapshot recording when an alarm condition occurs.

Printing is accomplished on 50 mm wide thermal paper at recorder speeds programmable up to 55 mm/s.

## 12.15 **ECG Processing**

The technique used in ECG senses the varying potential difference between two points at the skin surface which respond to the electro-chemical actions of the muscular activity of the heart.

Three electrodes are attached to the patient's right arm (RA), left arm (LA) and left leg (LL). The varying potentials at these locations are cable-connected to the ECG circuit inputs where they are conditioned, and the difference of potential between two selected leads is digitized before transmitting through opto-isolators to the processor. The processor-installed algorithms operate on the signals to develop drivers for the graphic display and to compute the heart rate in beats per minute (BPM).

In addition to the acquisition of the QRS waveform complex, the ECG input and subsequent signal processing computing circuitry perform a number of other functions:

- They detect a "lead-off" condition if one of the electrode connections is disrupted.
- They detect the presence of pacemaker signals within the QRS waveform complex of the ECG.

## 12.16 **ICG Processing**

ICG is a non-invasive means of obtaining and evaluating hemodynamic data by measuring cardiac flow rather than pressure.

ICG uses impedance cardiography with four sensors. Each sensor has two electrodes. The sensors are placed on specific areas on the neck and thorax to measure the change that occurs in a patient's thoracic fluid content.

- The outer electrodes inject a small electrical current (1 mA) through the thorax. This signal cannot be felt by the patient.
- The inner electrodes receive the transmitted signal to measure impedance.

As velocity and volume of blood in the aorta change, ICG measures the changes in impedance from systole to diastole to calculate hemodynamic parameters. Impedance, as it applies to ICG, is the resistance to the flow of an electrical current. Depending on the impedance to flow of the injected current, the monitor records changes and displays these changes in the impedance waveform.

ICG can be used to continuously monitor cardiac output, thoracic fluid content, stroke volume, and a variety of contractility indices.

### **12.17     *Respiration Processing***

The patient's respiration is detected by using two of the three leads of the ECG electrodes and cable. A low-level excitation signal is applied to these leads, and the variation of the thoracic impedance caused by the breathing is sensed and processed for display and measurement.

### **12.18     *NIBP Processing***

The NIBP processing uses an oscillometric technique to provide needed measurements at selected intervals. This technique uses an inflatable sphygmomanometer cuff similar to those used by clinicians in routine measurements.

A motorized pump inflates the cuff to approximately 180 mmHg initially, at which point the pressure effectively stops the flow of blood. Then, under monitor control, the pressure in the cuff is gradually reduced in steps, while a pressure transducer detects the air pressure and transmits the parameter signal to the NIBP input circuitry.

As the pressure is reduced, blood flows in the previously occluded artery, and changes the measurements made by the transducer. The point at which oscillation increases sharply is defined as systolic pressure. As the cuff continues to deflate, oscillation amplitude increases to a maximum, and then decreases. The peak oscillation amplitude is defined as the mean arterial pressure. The point at which the system detects a rapid decrease in oscillation is defined as the diastolic pressure.

### **12.19     *SpO<sub>2</sub> Processing***

Measurement of oxygen saturation in the blood uses a spectrophotometry technique. It is based on the fact that oxyhemoglobin differ in their absorption of red and infrared light, and that the volume of arterial blood in tissue changes during the pulse.

Using these facts, a pulse oximeter passes red and infrared light into an arteriolar bed and measures changes in light absorption during the pulsatile cycle. The light sources are red and infrared light emitting diodes (LEDs), while the detection is accomplished by a photo diode.

To identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and both blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The measurement is based upon the difference between maximum and minimum absorption, focusing on the pulsatile arterial blood.

### **12.20     *CO<sub>2</sub> Processing***

The Microstream CO<sub>2</sub> board consists of an micro Controller with memory, the Flow system (FilterLine recognition system, Inlet, solenoid valve), Measurement Cell (Exciter, IR Source, Detectors and Temp Sensor) and an analog section with ADC.

The gas inlet allows the connection of Microstream FilterLines. The FilterLines are detected by the Optical Code Recognition.

### **12.21     *Temperature Processing***

Measurement of patient temperature is accomplished by processing the signal from a probe containing a resistor whose impedance is temperature dependent. The class of such components is called thermistor.

The LIFEGARD II is designed to accept the signals from Series 400 probes manufactured by Yellow Springs Incorporated. Interchangeable probes in this series may be used for esophageal, rectal, skin or surface, or airway temperature measurement. Probes are furnished with a standard 10-foot lead. Extension leads are available.

The signal from the probe is conditioned by the monitor's input circuitry, processed, and used to drive the numeric display.

# Specifications

## 13.1 General

This chapter includes all hardware, regulatory, and measuring specifications for the monitor.

## 13.2 Hardware Specifications

Component	Specification
<b>Size (excluding handle)</b>	
Width	13.50 in (34.3 cm)
Height	10.25 in (26.0 cm)
Depth	7.50 in (19.0 cm)
Weight (excluding accessories, options, cables)	12.5 lb (5.7 kg)
<b>Display (cold cathode fluorescent backlight)</b>	
Screen Type	TFT (color)
Active Screen Size	8.3 x 6.2 in (210.8 x 157.5 mm): 10.4 in (264.2 mm) diagonally
Resolution	640 x 480 pixels
<b>Recorder</b>	
Type	Thermal
Weight	0.9 lb (.41 kg)
Paper Width	50 mm
Speeds	12.5, 25, and 50 mm/s

## 13.3 Safety Standards

Parameter	Specification
United States Federal Law restricts this device to sale by or on the order of a physician.	
CE Marking: Medical Device Directive, 93/42/EEC	
EN 60601-1, EN 60601-1-1, EN 60601-2-27, EN 60601-2-30, EN 60601-2-49, UL 60601-1, EN 60601-1-8, CAN/CSA C22.2 No. 601.1-M90, EN 864, ISO EN 9919	
Protection Class	Class I, internally and externally powered equipment, per IEC 60601-1, clause 2.2.4
Degree of Protection	Type CF, IPX1 per IEC 60601-1, clause 2.1.26
Mode of Operation	Continuous



## 13.4 Audible Alarms

Parameter	Specification
<b>High Priority Alarm</b>	
Frequency Component	625 Hz base frequency; 1250 Hz, 1875 Hz, 2500 Hz and 3125 Hz harmonics
Sound Pressure	>45 dBa and <80 dBa; ≥Medium Priority Alarm, ≥Low Priority Alarm
<b>Medium Priority Alarm</b>	
Frequency Component	550 Hz base frequency; 1100 Hz, 1650 Hz, 2200 Hz and 2750 Hz harmonics
Sound Pressure	>45 dBa and <80 dBa; ≤High Priority Alarm, ≥Low Priority Alarm
<b>Low Priority Alarm (Physiological)</b>	
Frequency Component	450 Hz base frequency; 900 Hz, 1350 Hz, 1800 Hz and 2250 Hz harmonics
Sound Pressure	>45 dBa and <80 dBa; ≤High Priority Alarm, ≤Medium Priority Alarm

## 13.5 Electrical

Parameter	Specification
<b>Power Sources</b>	
Internal Battery	12 volt, 4.5 Ah, sealed, lead-acid
Battery Operating Time	3 hours, fully charged battery at 25°C (without EtCO <sub>2</sub> ) under normal conditions (one NIBP measurement every 15 minutes, all other modes active); 45 minutes if printing continuously. 1 hour, fully charged battery at 25°C (with EtCO <sub>2</sub> ) under normal conditions; 30 minutes if printing continuously.
AC Mains	100 to 240 VAC, 50-60 Hz, 1 A max

## 13.6 Environmental

Parameter	Specification
Mechanical Shock	IEC 60068-2-27; 100g, 6 ms, 3 axes, 18 total shocks, non-operating
Mechanical Vibration	IEC 60068-2-6; Sinusoidal; 10-58 Hz, 0.15 in displacement; 58-150 Hz, 2g acceleration; 4 min/sweep; 20 sweeps/axis, non-operating
Water Resistance	IEC 60529 Classification IPX1 (Protected against vertically dripping water)
Electromagnetic Compatibility	Radiated and conducted electromagnetic energy per CISPR II, Class B <sup>a</sup>
<b>Thermal</b>	
Operating	5 to 45°C (41 to 113°F)
Storage <sup>b</sup>	-20 to 60°C (-4 to 140°F)
<b>Humidity</b>	
Operating	5 to 90% RH, non-condensing
Storage	5 to 95% RH, non-condensing

a. Devices are suitable for connection to public low-voltage distribution systems.

b. For ECG electrodes and ICG sensors storage temperature is 5 to 30°C (41 to 86°F).

## 13.7 Measuring and Displaying Parameters

Parameter	Specification
Heart Rate Range	20-250 b/min
Heart Rate Accuracy	±1 b/min per AAMI EC 13-2002
Bandwidth: Normal Monitoring	0.5 Hz - 40 Hz
Bandwidth: Extended Low Frequency Range (user selectable)	0.05 Hz - 40 Hz
Leads	3 lead, user selectable
Display Sweep Speeds	12.5, 25, and 50 mm/s
Pacemaker Detection	Indicator on waveform display, user selectable
ECG size (sensitivity)	0.5, 1, 2, 4 mV/cm
Lead-off Condition	detected and displayed
Input Impedance	>5 MΩ
CMRR (Common Mode Rejection Ratio)	>90 dB at 50 or 60 Hz
Input Dynamic Range	±5 mV AC, ±300 mV DC
Defibrillator Discharge	<5s per IEC 60601-2-27
Recovery	<5s per AAMI EC13-2002

**ECG Standards**

Standards		
Meets the performance standards of ANSI/AAMI EC13-2002. Instead of a 1 mV standardizing voltage (section 4.2.2.9), a fixed, 1 cm reference bar is always present in the ECG display, along with the ECG size setting expressed in mV/cm. The following information references particular sections of ANSI/AAMI EC13-2002		
Respiration waveform. 4.1.2.1 (b)	A 76.8 kHz square wave is used to inject 50 $\mu$ A p-p differentially between RA and LL.	
Leads-off Sensing	<100 nA DC current	
Tall T-wave rejection. 4.1.2.1 (c)	T-wave of 0.8 mV amplitude will not affect heart rate determination.	
Heart rate averaging. 4.1.2.1 (d)	Averages six of the most recent eight detected R-R intervals excluding the longest and shortest of the eight intervals.	
Response to irregular rhythms 4.1.2.1 (e)	a) Ventricular bigeminy - 80 b/min rhythm. b) Slow alternating ventricular bigeminy - 60 b/min c) Rapid alternating ventricular bigeminy - 80 to 103 b/min d) Bi-directional systoles - 134 to 151 b/min	
Heart rate meter response time.	a) Change from 80 to 120 b/min: 4 to 5s b) Change from 80 to 40 b/min: 6 to 8s	
Time to alarm for tachycardia. 4.1.2.1 (g)	Waveform 4(a) Amplitude • 0.5 mV • 1.0 mV • 2.0 mV	Average Time to Alarm • 6.6s • 4.0s • 2.2s
	Waveform 4(b) Amplitude • 1.0 mV • 2.0 mV • 4.0 mV	Average Time to Alarm • 3.0s • 1.4s • 1.0s

Standards		
Pacemaker pulse rejection. 4.1.4.1, 4.1.4.2	With the exceptions noted below, the monitor will reject all single and double pacemaker pulses either 150 or 250 ms apart of amplitudes $\pm 2$ to $\pm 700$ mV from 0.1 to 2.0 ms, with and without under/overshoot. Following are pacer pulse conditions that the monitor will reject, but which are less than the maximum range listed in the standard:	
	Pacer pulse width = 2 ms, Double pulse either 150 or 250 ms apart, without over/undershoot, no QRS	Pacer amplitude $\leq \pm 400$ mV
	Pacer pulse width = 2 ms, Double pulse 250 ms apart, without over/undershoot, ineffective pacer	Pacer amplitude $\leq \pm 500$ mV
	Pacer pulse width = 2 ms, Single or Double pulse either 150 or 250 ms apart, with 2 mV over/undershoot, no QRS.	Pacer amplitude $\leq \pm 100$ mV
	Pacer pulse width = 2 ms, 250 ms spaced double pulse, with 2 mV over/undershoot, effective pacing.	Pacer amplitude $\leq \pm 200$ mV
	Pacer pulse width = 2 ms, 150 ms spaced double pulse, with 2 mV over/undershoot, ineffective pace.	Pacer amplitude $\leq \pm 90$ mV
	Pacer pulse width = 2 ms, 250 ms spaced double pulse, with 2 mV over/undershoot, ineffective pace.	Pacer amplitude $\leq \pm 160$ mV
	Pacer pulse width = 2 ms, Double pulse 150 ms apart with 2 mV undershoot (positive pulse only) effective pacer.	Pacer amplitude $\leq \pm 600$ mV
	Pacer pulse detector rejection of fast ECG signals.	50% pacer pulses triggered for ECG rise times of 5 volts/second

**Respiration**

Parameter	Specification
Technique	Trans-thoracic impedance
Range	3 to 150 breaths/min
Accuracy	±3 breaths/min
Leads	RA to LL
Display Sweep Speeds	6.25, 12.5, 25 mm/s
Lead Off Condition	Detected and displayed

**NIBP (Non-Invasive Blood Pressure)**

Parameter	Specification
Standards	Meets performance standards of ANSI/AAMI SP10-2002
Technique	Oscillometric
Maximum Cuff Pressure	300 mmHg
Cuff Pressure Display Range	–10 to +330 mmHg
Pulse Rate Range	40 to 200 b/min
Blood Pressure Accuracy	Mean error and standard deviation per ANSI/AAMI SP10-2002 <sup>a</sup>
Pulse Rate Accuracy	Greater of ±2 bpm or ±2%
Factory Default Initial Cuff Inflation	160 mmHg (adult mode); 120 mmHg (pediatric mode)
Subsequent Cuff Inflation	Prev SYS ±30 mmHg
<b>Blood Pressure Measurement Display Range</b>	
Systolic	40 to 250 mmHg
Diastolic	20 to 200 mmHg
Mean Arterial Pressure	27 to 220 mmHg
<b>Measurement Modes</b>	
Auto	Automatic measurements at intervals of 1, 3, 5, 10, 15, 30, 60 and 90 minutes
Manual	Single measurement initiated by Start/Stop button
STAT	Series of consecutive measurements for 5 minutes

a. Systolic and Diastolic blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method.

**Temperature**

Parameter	Specification
Technique	Probe, YSI 400 Series Thermistor
Range	15 to 45°C (59 - 113°F)
Accuracy	±0.1°C (±0.18°F)

***SpO<sub>2</sub>***

<b>Parameter</b>	<b>Specification</b>
Technique	<i>OxiMax</i> Sensors
<b>Range</b>	
% Saturation	1% to 100%
Pulse Rate	20 to 300 b/min
<b>Accuracy</b>	
SpO <sub>2</sub>	0 - 69% not specified; 70%-100% ±3 digits
Pulse Rate – 20 to 250 b/min	±3 b/min (>250 b/min not specified)
<b>Display Update Period</b>	1 second
<b>Calibration</b>	functional

<b><i>OxiMax</i> Sensors</b>	
Wavelength	660 nm and 890 nm
Energy	Not exceeding 15 mW

**CO<sub>2</sub>**

Complies with EN 864/ISO 9918

Parameter	Specification
Technique	The CO <sub>2</sub> module, together with the appropriate FilterLine
Range	0 to 98 mmHg (0 to 13 kPa), or 13% EtCO <sub>2</sub> whichever is lower.
Flow Rate	50 ±7.5 ml/min
Warm-up Time	180s max.; typically 30s
Gas Sampling Delay Time	2.7s
<b>Resolution</b>	
Numeric	1.0 mmHg (0.1 kPa)
Wave	0.1 mmHg (0.01 kPa)
Rise Time	190 ms for adult mode (measured with sample line for humidified ventilation and airway adapter for adult)
Calibration Interval	4,000 operating hours
Auto Zero Intervals	<2% duty cycle. Increases if the temperature changes by 8°C from the previous Auto-Zero interval, or the pressure changes by 45 mmHg.
Leak Tightness	<40 mbar/min with 30% vacuum
<b>Accuracy<sup>a</sup></b>	
0 - 20 minutes	0 to 38 mmHg ±4 mmHg; 38 to 99 mmHg ±12% of indicated value
>20 minutes	0 to 38 mmHg ±2 mmHg 38 to 99 mmHg ±5% of indicated value + 0.08% for every 1.0 mmHg above 40 mmHg.

a. Accuracy applies for respiration rate up to 80 b/min. For respiration rate above 80 b/min, the accuracy complies with EN 864/ISO 9918 (4 mmHg or ±12% of indicated value, whichever is greater) for End-tidal CO<sub>2</sub> values exceeding 19 mmHg. The above accuracy is maintained to within 4% for the following gas mixtures: CO<sub>2</sub>: 0 - 13%; N<sub>2</sub>: 0 - 97.5%; O<sub>2</sub>: 0 - 100%; N<sub>2</sub>O: 0 - 80%; H<sub>2</sub>O: Dry to saturated.

**awRR**

Parameter	Specification
Range	0 to 150 breaths/min
Accuracy	0 to 41 breaths/min ±1 breaths/min; 41 to 70 breaths/min ±2 breaths/min; 71 to 100 breaths/min ±3% of reading >100 breaths/min ±5% of reading

**ICG**

Parameter	Specification
ICG Measurement technique	TEB (thoracic electrical bioimpedance)
Number of Electrode pairs	4
Excitation Current	1 mA RMS $\pm 10\%$
Excitation Frequency	76.8 kHz, $\pm 0.01\%$
Basic Thoracic Impedance Range	0-60 $\Omega$
Basic Impedance Measurement Bandwidth	0-10 Hz
Impedance Variation Range	$\pm 1\Omega$
Impedance Noise	<1 m $\Omega$ at 50 $\Omega$ basic impedance
<b>Patient Criteria</b>	
Height	4 ft - 7 ft, 6 in (122 - 229 cm)
Weight	67 - 350 lb (30 - 159 kg)

**Trends**

Parameter	Specification
Type	Graphical and tabular
Memory Storage	12 hours, nonvolatile
Data interval	20 seconds (stored data points is the average over 20-second interval)
<b>Graphical Trend</b>	
Format	One graph per vital sign
Display range	2 hours, scrollable
<b>Vertical scaling</b>	
Heart Rate	50-100, 0-250, 25-125 b/min
NIBP	50-100, 0-150, 0-300 mmHg
SpO <sub>2</sub>	0-100, 60-100, 80-100%
EtCO <sub>2</sub>	0-100, 0-60, 20-50 mmHg
Respiration Rate	0-20, 0-50, 0-150 b/min
Temperature °C	15-45, 33-41, 35-39°C
Temperature °F	55-115, 91-107, 96-102°F
Tabular format	One table for all variables. Six fields per row (time and five vital signs)
Display interval	Per NIBP interval, or every 20 minutes when not measuring NIBP.

# Technical Services and Support

## 14.1 **General**

Appendix E includes instructions for obtaining technical assistance and for returning the LIFEGARD II monitor for repairs.

## 14.2 **Obtaining Technical Assistance**

The Life Care Systems Support Group is the resource for providing installation, preventative and corrective maintenance, technical and operator support, and parts, and documentation provisioning for Analogic-supplied products.

To Contact the Life Care Systems Support Group:

Call: +1 978-326-4000 (MA and International)

Spare Parts: +1 978-326-4700 (MA and International)

Repair: +1 978-326-4700 (MA and International)

Technical Assistance: +1 978-326-4170 (MA and International); 800-977-6929 (U.S.)

Fax: +1 978-977-6854 (MA and International)

email: lcssupport@analogic.com

## 14.3 **Return Material Procedure**

To return a defective product to Analogic, you will need to obtain a Return Material Authorization (RMA) number from our Life Care Systems Support Group. Please contact a Service Coordinator at:

Call: +1 978-326-4700

Fax: +1 978-977-6854

email: lcssupport@analogic.com

You will need to supply the Service Coordinator with the following information:

- The Model number(s) and Serial number(s) of the product,
- The quantity of items,
- The "Bill to" address for invoice purposes,
- The "Ship to" address,
- A Purchase Order number, and
- Details of the reported failure.

The Service Coordinator will then inform you of:

- The Return Material Authorization (RMA) number,
- The warranty or non-warranty status of the units being returned,
- Any repair charge.



All returned material must be shipped “PREPAID” to the following address:

Analogic Corporation  
Life Care Systems  
8 Centennial Drive  
Peabody, MA 01960  
Attn: Receiving Dock B  
RMA#:\_\_\_\_\_

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**NOTE**

Please reference your RMA number on both your purchase order and the shipping label.

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Analogic Corporation  
Life Care Systems Division  
8 Centennial Drive  
Peabody, MA 01960-7987, USA  
Tel: 978-326-4000

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